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**Wyeth**

Five Giralda Farms
Madison, NJ 07940

**Ronald J. Schott, Esq.**
Corporate Counsel
Environment, Health & Safety
973-660-6641 tel
973-660-7176 fax



September 29, 2005



**VIA OVERNIGHT MAIL**
Ms. Carlyn Winter Prisk (3HS62)
U.S. Environmental Protection Agency
1650 Arch Street
Philadelphia, PA 19103

**RE: Follow-up 104 (e) Request – Wyeth**
**Lower Darby Creek Area Superfund Site**
**Delaware and Philadelphia Counties, Pennsylvania**

Dear Ms. Prisk:

Enclosed please find Wyeth's response to the 1 August 2005 correspondence from Mr. Abraham Ferdas of the United States Environmental Protection Agency ("USEPA") Region 3 Office regarding the Lower Darby Creek Area Superfund Site (the "Site"). Please note that Wyeth was granted an extension by USEPA up to, and including, September 30, 2005 to provide this response.

Although the USEPA Follow-up 104(e) Request makes reference to "attached documents," the correspondence contained no such documents. Nonetheless, based on our review of our prior responses to USEPA in this matter, we assume USEPA is referencing the document at Exhibit A. Because this document relates only to the Wyeth facility located in West Chester, Pennsylvania, we have limited or response to that facility.

This response shall not be construed as an admission of any fact or liability. Further, this response shall not be construed as a waiver of any rights or defenses available to Wyeth, its subsidiaries and/or affiliates whether statutory or otherwise at law. Due to the broad nature of USEPA's request, our investigation of this matter, by necessity, continues. As such, should we identify and locate additional, relevant information, Wyeth reserves the right to supplement this response as appropriate.

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If you have any questions, or require any further information, please call me at your convenience. Please continue to address all future correspondence concerning this matter to my attention.

Very truly yours,

Ronald J. Schott

Enclosures

cc: G. Smith, Esq.
R. Taggart

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## INTRODUCTORY STATEMENT

Wyeth's investigation in this matter continues. If responsive information is developed through this continued investigation Wyeth will supplement or amend this response as appropriate.

## GENERAL OBJECTIONS

Wyeth objects to this Follow-up 104(e) Request (the "Follow-up RFI") in general as overbroad, unduly burdensome, and beyond the scope of information authorized to be obtained pursuant to Section 104(e)(2) of CERCLA.

## FOLLOW-UP REQUEST FOR INFORMATION

EPA hereby requests that Wyeth fully explain what comprised the "supervised destruction" of "production rejects" as referenced in the attached documents. Additionally, please answer Questions six (6) and seven (7) of the August 9, 2002 Information Request (attached) for only the referenced production rejects during the time period 1969 through 1974.

**RESPONSE:**

Wyeth objects to USEPA's follow-up question as vague, ambiguous, overbroad, unduly burdensome and beyond the scope of information authorized to be obtained pursuant to Section 104(e)(2) of CERCLA, particularly to the extent: (i) that USEPA did not attach any documents to which it was apparently referring and (ii) that it requires Wyeth to create or obtain information that is not in its reasonable control. Without waiving the foregoing objections, Wyeth responds as follows.

Wyeth identified and contacted a number of former employees, as well as one current employee, in an attempt to ascertain what comprised the "supervised destruction" of "production rejects," as those terms were used in the document at Exhibit A. Of the individuals interviewed, they either had no personal knowledge of, or could not recall, with any specificity, what comprised supervised destruction of production rejects during the time period 1969 through 1974. Nonetheless, and in light of the foregoing limitations, it is Wyeth's understanding that supervised destruction most likely referred to the process of overseeing the on-site destruction and, in certain instances, the transportation and disposal of certain materials and rejected products in connection with the manufacture of pre-filled sterile disposable syringes at the West Chester, Pennsylvania location. These materials might have included printed material (boxes, product insert information pages, labels) that contain references to the product name, lot number, or expiration date; unfilled, unused syringe component rejects (glass barrels, needles, stoppers); and/or filled (i.e., dosage form) production rejects. These materials might also have included laboratory and stability program samples. In particular, products that would have been managed

in the foregoing manner would have included those products designated as controlled dangerous substances by the U.S. Drug Enforcement Administration.

Each manufacturing area that generated these materials accumulated them in specially marked containers, and then transferred them to a collection area at the site. There, preparations would begin to destroy and, in some cases, consequently ship, these materials to their eventual disposal outlet. A person was designated to witness the on-site destruction and, in some cases, accompany the shipment to the disposal destination and witness the final destruction/disposal.

In addition, it is Wyeth's understanding that the products at its West Chester, Pennsylvania during the time period 1969 through 1974 that might have been managed through supervised destruction, as well as the ancillary materials with respect to those products, are identified at Exhibit B.

**QUESTION 6 FROM August 9, 2002 Information Request**

6. Identify every hazardous substance used, generated, purchased, stored, or otherwise handled at your establishment(s) in the Philadelphia, Pennsylvania area between 1958 and 1976. Provide chemical analyses and Material Safety Data Sheets ("MSDS"). With respect to each such hazardous substance, further identify:

a. The process(es) in which each hazardous substance was used, generated, purchased, stored, or otherwise handled;

b. The chemical composition, characteristics, and physical state (solid, liquid, or gas) of each such hazardous substance;

c. The annual quantity of each such hazardous substance used, generated, purchased, stored, or otherwise handled;

d. The beginning and ending dates of the period(s) during which such hazardous substance was used, generated, purchased, stored, or otherwise handled;

e. The types and sizes of containers in which these substances were transported and stored; and

f. The persons or companies that supplied each such hazardous substance to your company.

**RESPONSE:**

**(Note: Pursuant to the Follow-up RFI, this response has been limited to the time period 1969 through 1974 and to "production rejects," as that term is understood by Wyeth.)** Wyeth generally objects to Questions 6 and 6(a) – 6(f) as vague, overbroad and beyond the scope of information authorized to be obtained pursuant to Section 104(e)(2) of CERCLA particularly as the term "hazardous substance" might require a legal conclusion. Without waiving said objections, and except as may otherwise be set forth herein or in the Exhibits

hereto, Wyeth has attached as Exhibit C the MSDS for the "production rejects," as that term is understood by Wyeth, in connection with its West Chester, Pennsylvania facility and for the time period of 1969 to 1974. Responding further, Wyeth states, with respect to any hazardous substances that might have been related to the production rejects, and except as may otherwise be set forth herein or in the Exhibits hereto, it has been unable to identify information responsive to Questions 6, (a) - (f), inclusive.

**QUESTION 7 FROM August 9, 2002 Information Request**

7. Identify all by-products and wastes generated, stored, transported, treated, disposed of, released, or otherwise handled by your establishment(s) in the Philadelphia, Pennsylvania area between 1958 and 1976. With respect to each such by-product and waste identified, further provide:

a. The process(es) in which each such by-product and waste was generated, stored, transported, treated, disposed of, released, or otherwise handled;

b. The chemical composition, characteristics, and physical state (solid, liquid, or gas) of each such by-product or waste;

c. The annual quantities of each such by-product and waste generated, stored, transported, treated, disposed of, released, or otherwise handled;

d. The types, sizes, and numbers of containers used to treat, store, or dispose of each such by-product or waste;

e. The name of the individual(s) and/or company(ies) that disposed of or treated each such by-product or waste; and

f. The location and method of treatment and/or disposal of each such by-product or waste.

**RESPONSE:**

**(Note: Pursuant to the Follow-up RFI, this response has been limited to the time period 1969 through 1974 and to "production rejects," as that term is understood by Wyeth.)** Wyeth objects to Questions 7 and 7(a)-7(f) as vague, overbroad unduly burdensome, and beyond the scope of information authorized to be obtained by USEPA pursuant to Section 104(e)(2) particularly as the term "waste" is defined in the Follow-up RFI and the term "by-products" is not. Without waiving said objections and except as may otherwise be set forth herein or in the Exhibits hereto, Wyeth states that, in connection with its West Chester, Pennsylvania facility and for the time period of 1969 to 1974, it has been unable to locate any of the requested information regarding "production rejects," as that term is understood by Wyeth.

EXHIBIT A

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Mr. R. Whiteoak
W. Menhennett

[illegible] Merrion
[illegible]. Badrak

# INTERNAL CORRESPONDENCE

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| | | | |
|---|---|---|---|
| Mr. Larry Hewlett | | from | J. D. Johnson |
| WLI | located W.C. Pa. | company | WLI located W.C., Pa. |
| Object | Disposal Solid Wastes | date | April 12, 1973 |

Dear Larry;

You will remember our very brief discussion of the matter of plant accumulations of ordinary trash and other waste materials generated at our plant and disposition of the same.

Our Central Engineering is now interested in overall solid waste problems at West Chester, Great Valley, and Radnor. Mr. Ray Whiteoak has been assigned to the project and has contacted this writer for information. This will also help him in his assignment.

Information on disposal activities in which the warehouse and transportation department has a primary responsibility has been compiled over a period of time. Attached are several information sheets detailing methods and indicating the scope of several disposal activities.

Ordinary Trash Accumulations
Non - Ordinary Trash Disposal
"Supervised Destruction" - Printed Materials
"Supervised Destruction" - Production Rejects, etc.

In addition the department assists in other disposal activities where actual disposal arrangements are made by others. One such is in "Disposal of Liquids in Drums" where disposal arrangements are made by our Environmental Control Group. Warehouse and transportation involvement is shown on an attached sheet.

For overall safety reasons we are about to start a program of transportation assistance to the Radnor facility. We will pick up approx. 20-25 five gallons cans of solvents, etc., twice monthly and haul them to West Chester. Environmental Control group will empty the containers. We will return them, when empty, to G.V.L. for pick up there by the Radnor shuttle vehicle.

No attempt is made to comment on other Plant Disposal Activities.

It should be noted our program for "Supervised Destruction" of production rejects, etc., is in some difficulty. The facility used from February 1969 until now (Tri-County Hauling Co., Phila., Pa.) has had their landfill operation closed down by Authorities. An alternate site (Knickerbocker Landfill, Malvern, Pa.) has been used once (04-10-73).

The Knickerbocker Landfill enjoys a virtual monopoly in the area. It is geared to mass disposal operations. We anticipate cost problems. We also anticipate problems in receiving the special disposal attention at the Landfill which we feel is necessary in this particular disposal program.

Wyeth
SERVICE TO MEDICINE

Encl.

J. D. Johnson

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EXHIBIT B

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**Exhibit B**

Ativan Injection—Refer to "Lorazepam"
Bacteriostatic Sodium Chloride
Bicillin CR—Refer to "Bicillin"
Bicillin LA—Refer to "Bicillin"
Codeine Phosphate Injection
Digoxin Injection
Diphenhydramine HCI Injection
Diphenhydrinate Injection—MSDS not available
Heparin Sodium Injection
Heparin Lock Flush Injection—Refer to "Heparin Sodium"
Hydromorphone HCI Injection
Mepergan Injection
Meperidine HCI Injection
Morphine Sulfate Injection
Nafcillin Sodium Monodhydrate, Bulk
Normiflo Injection—Refer to "Heparin Sodium"
Omnipen Injection
Penicillin G Benzathine, Bulk
Penicillin G Procaine, Bulk
Pentobarbital Sodium Injection
Phenergan Injection
Phenobarbital Sodium Injection
Polyflex Injection—Refer to "Ampicillin Trihydrate"
Secobarbital Sodium Injection
Sterile Ampicillin Sodium, Bulk
Unipen Injection
Wycillin Injection

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EXHIBIT C

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MATERIAL SAFETY DATA SHEET

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PATIONAL HEALTH SERVICES, INC.
WEST 42ND STREET, 12TH FLOOR
EW YORK, NEW YORK 10036
-800-445-MSDS (1-800-445-6737) OR
-212-789-3535

FOR EMERGENCY SOURCE INFORMATION
CONTACT: 1-615-366-2000 USA

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## SUBSTANCE IDENTIFICATION

CAS NUMBER: 846-49-1
RTECS NUMBER: DF0350000

BSTANCE: LORAZEPAM

ADE NAMES/SYNONYMS:
2H-1,4-BENZODIAZEPIN-2-ONE, 7-CHLORO-5-(2-CHLOROPHENYL)-1,3-DIHYDRO-3-HYDROXY-;
7-CHLORO-5-(2-CHLOROPHENYL)-1,3-DIHYDRO-3-HYDROXY-2H-1,4-BENZODIAZEPIN-2-ONE;
2H-1,4-BENZODIAZEPIN-2-ONE, 7-CHLORO-5-(ORTHO-CHLOROPHENYL)-1,3-DIHYDRO-3-HYDROXY-;
7-CHLORO-5-(ORTHO-CHLOROPHENYL)-1,3-DIHYDRO-3-HYDROXY-2H-1,4-BENZODIAZEPIN-2-ONE;
ATIVAN; ORTHO-CHLOROOXAZEPAM; ORTHO-CHLOROXAZEPAM; TAVOR; TEMESTA; WY 4036;
WYPAX; DEA 2885; C15H10CL2N2O2; OHS12985

EMICAL FAMILY:
odiazepine

LECULAR FORMULA: C15-H10-CL2-N2-O2

LECULAR WEIGHT: 321.16

RCLA RATINGS (SCALE 0-3): HEALTH=2 FIRE=1 REACTIVITY=0 PERSISTENCE=3
PA RATINGS (SCALE 0-4): HEALTH=U FIRE=1 REACTIVITY=0

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## COMPONENTS AND CONTAMINANTS

MPONENT: LORAZEPAM PERCENT: 100.0
CAS# 846-49-1

HER CONTAMINANTS: NONE

POSURE LIMITS:

RAZEPAM:
Subject to California porposition 65 cancer and/or reporductive toxicity warning and release requirements-(July 1,1990)

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## PHYSICAL DATA

SCRIPTION: White to off-white crystalline powder.

LTING POINT: 331-334 F (166-168 C) SPECIFIC GRAVITY: not available

)LUBILITY IN WATER: 0.08%

)LVENT SOLUBILITY: Soluble in ethyl acetate, propylene glycol, alcohol; ...htly soluble in chloroform.

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## FIRE AND EXPLOSION DATA

:RE AND EXPLOSION HAZARD:
.ight fire hazard when exposed to heat or flame.

:REFIGHTING MEDIA:
'y chemical, carbon dioxide, water spray or regular foam
.993 Emergency Response Guidebook, RSPA P 5800.6).

r larger fires, use water spray, fog or regular foam
993 Emergency Response Guidebook, RSPA P 5800.6).

REFIGHTING:
ve container from fire area if you can do it without risk. Do not scatter
illed material with high-pressure water streams. Dike fire-control water for
ter disposal (1993 Emergency Response Guidebook, RSPA P 5800.6, Guide
ge 31).

e agents suitable for type of surrounding fire. Avoid breathing hazardous
pors, keep upwind.

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## TOXICITY

RAZEPAM:
XICITY DATA: 71 ug/kg oral-child TDLo; 21 ug/kg oral-human TDLo; 380
ug/kg/19 days-intermittent oral-woman TDLo; 4500 mg/kg oral-rat LD50;
1850 mg/kg oral-mouse LD50; 870 mg/kg intraperitoneal-rat LD50;
1810 mg/kg intraperitoneal-mouse LD50; reproductive effects data (RTECS).
RCINOGEN STATUS: None.
)TE TOXICITY LEVEL: Moderately toxic by ingestion.
RGET EFFECTS: Central nervous system depressant.
INCREASED RISK FROM EXPOSURE: Persons with liver or renal impairment, acute
narrow-angle glaucoma, hypersensitivity to benzodiazepines, personality
disorders, or history of drug abuse.*
)ITIONAL DATA: The use of alcoholic beverages may enhance the toxic effects.
Interactions with medications have been reported. Poisoning may impair tasks
requiring alertness. May cross the placenta and may be excreted in human
)reast milk.*

lay be based on general information on benzodiazepines.

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## HEALTH EFFECTS AND FIRST AID

(ALATION:
'AZEPAM:
_UTE EXPOSURE- No data available.
:HRONIC EXPOSURE- No data available.

RST AID- Remove from exposure area to fresh air immediately. Perform artificial respiration if necessary. Keep person warm and at rest. Treat symptomatically and supportively. Get medical attention immediately.

CONTACT:
RAZEPAM:
ACUTE EXPOSURE- No data available.
CHRONIC EXPOSURE- No data available.

RST AID- Remove contaminated clothing and shoes immediately. Wash with soap or mild detergent and large amounts of water until no evidence of chemical remains (at least 15-20 minutes). Get medical attention immediately.

E CONTACT:
RAZEPAM:
ACUTE EXPOSURE- No data available.
CHRONIC EXPOSURE- No data available.

RST AID- Wash eyes immediately with large amounts of water or normal saline, occasionally lifting upper and lower lids, until no evidence of chemical remains (at least 15-20 minutes). Get medical attention immediately.

GESTION:
RAZEPAM:
See information on benzodiazepines. In addition, LDH elevation may occur. Partial airway obstruction may result from overdoses. Reproductive effects have been reported in animals and humans.

ODIAZEPINES:
RCOTIC.
ACUTE EXPOSURE- The possible effects may include headache, nausea, vomiting, epigastric distress, diarrhea, incontinence, drowsiness, fatigue, dizziness, weakness, muscle relaxation, ataxia, dysarthria, change in salivation, slurred speech, a bitter taste, dilated pupils, diplopia, nystagmus and blurred vision. Irritability, impaired mental and psychomotor function, hallucinations, impaired recent memory, and anterograde amnesia may occur. Joint and chest pain have been reported. With larger doses, especially in severe intoxications, there may be an initial excitement and then sedation which may progress to stupor and possibly coma. Hypotension and tachycardia or bradycardia may occur. Rarely, respiratory or circulatory depression and death occur.
HRONIC EXPOSURE- In addition to the effects of acute exposure, repeated ingestion of benzodiazepines has been reported to cause a low incidence of other effects including paradoxical reactions such as anxiety and stimulation, skin rashes, urticaria, edema, and blood dyscrasias including agranulocytosis some of which may be hypersensitivity reactions. Hepatic reactions and jaundice, menstrual irregularities, anovulation, and impaired sexual function may also occur. Prolonged use of benzodiazepines may produce psychological or physical dependence. Abrupt cessation may result in withdrawal. Benzodiazepines may cross the placenta and may be excreted in breast milk and may result in neonatal withdrawal. An association between congenital malformations and use of minor tranquilizers during pregnancy has been suggested. Reported malformations include oral cleft, inguinal hernia, cardiac defects, microcephaly and retardation, pyloric stenosis, and duodenal atresia.

ST AID- Remove by ipecac emesis followed by administration of activated

charcoal. Airway-protected gastric lavage is necessary in patients with depressed respiration. Maintain blood pressure (Dreisbach, Handbook of Poisoning, 12th Ed.). Administration of gastric lavage should be performed qualified medical personnel. Get medical attention immediately.

NTIDOTE:
) specific antidote. Treat symptomatically and supportively.

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## REACTIVITY

EACTIVITY:
:able under normal temperatures and pressures.

ICOMPATIBILITIES:
)RAZEPAM:
OXIDIZERS (STRONG): Fire and explosion hazard.

ICOMPOSITION:
ıermal decomposition products may include toxic oxides of nitrogen and carbon ıd toxic and corrosive fumes of chlorides.

)LYMERIZATION:
ızardous polymerization has not been reported to occur under normal ımperatures and pressures.

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## STORAGE AND DISPOSAL

rve all federal, state and local regulations when storing or disposing this substance.

**Storage**

orage of controlled substances must comply with applicable security quirments in 21 CFR 1301.71, 1301.72, 1301.73, 1301.74, 1301.75 and 1301.76.

ore away from incompatible substances.

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## CONDITIONS TO AVOID

y burn but does not ignite readily. Avoid contact with strong oxidizers, cessive heat, sparks, or open flame.

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## SPILL AND LEAK PROCEDURES

TER SPILL:
e California Safe Drinking Water and Toxic Enforcement Act of 1986 roposition 65) prohibits contaminating any known source of drinking water th substances known to cause cancer and/or reproductive toxicity.

'PATIONAL SPILL:
.ep up and place in suitable clean, dry containers for reclamation or later sposal. Do not flush spilled material into sewer. Keep unnecessary people ay.

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PROTECTIVE EQUIPMENT

LATION:
ovide local exhaust or general dilution ventilation system.

SPIRATOR:
e following respirators are recommended based on information found in the physical data, toxicity and health effects sections. They are ranked in order from minimum to maximum respiratory protection.
e specific respirator selected must be based on contamination levels found in the work place, must be based on the specific operation, must not exceed the working limits of the respirator and must be jointly approved by the National Institute for Occupational Safety and Health and the Mine Safety and Health Administration (NIOSH-MSHA).

Any dust and mist respirator.

Any air-purifying respirator with a high-efficiency particulate filter.

Any powered air-purifying respirator with a dust and mist filter.

Any powered air-purifying respirator with a high-efficiency particulate filter.

Any type 'C' supplied-air respirator operated in the pressure-demand or other positive pressure or continuous-flow mode.

Any self-contained breathing apparatus.

FIREFIGHTING AND OTHER IMMEDIATELY DANGEROUS TO LIFE OR HEALTH CONDITIONS:

Any self-contained breathing apparatus that has a full facepiece and is operated in a pressure-demand or other positive-pressure mode.

Any supplied-air respirator that has a full facepiece and is operated in a pressure-demand or other positive-pressure mode in combination with an auxiliary self-contained breathing apparatus operated in pressure-demand or other positive-pressure mode.

THING:
loyee must wear appropriate protective (impervious) clothing and equipment prevent repeated or prolonged skin contact with this substance.

VES:
loyee must wear appropriate protective gloves to prevent contact with this stance.

PROTECTION:
loyee must wear splash-proof or dust-resistant safety goggles to prevent contact with this substance.

gency eye wash: Where there is any possibility that an employee's eyes may exposed to this substance, the employer should provide an eye wash ntain within the immediate work area for emergency use.

CREATION DATE: 03/13/89 REVISION DATE: 06/30/94

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# MATERIAL SAFETY DATA SHEET

## 1. CHEMICAL PRODUCT AND COMPANY IDENTIFICATION

**MDL INFORMATION SYSTEMS, INC.**
**1281 Murfreesboro Road, Suite 300**
**Nashville, TN 37217-2423**

**1-615-366-2000**

**EMERGENCY TELEPHONE NUMBER**
**1-800-424-9300 (NORTH AMERICA)**
**1-703-527-3887 (INTERNATIONAL)**

**SUBSTANCE: SODIUM CHLORIDE**

**TRADE NAMES/SYNONYMS:**
SODIUM MONOCHLORIDE; SODIUM CHLORIDE (NaCl); SALT, WHITE CRYSTALS, SOLAR; BULK INDUSTRIAL CRUDE SOLAR; COMMON SALT; ROCK SALT; TABLE SALT; SEA SALT; SALT; HALITE; ClNa; OHS21105; RTECS VZ4725000

**CHEMICAL FAMILY:** inorganic, salt

**CREATION DATE:** Feb 04 1985
**REVISION DATE:** Jun 16 2005

## 2. COMPOSITION, INFORMATION ON INGREDIENTS

**COMPONENT:** SODIUM CHLORIDE
**CAS NUMBER:** 7647-14-5
**EC NUMBER (EINECS):** 231-598-3
**PERCENTAGE:** 100

## 3. HAZARDS IDENTIFICATION

**NFPA RATINGS (SCALE 0-4):** HEALTH=2 FIRE=0 REACTIVITY=0


**EMERGENCY OVERVIEW:**
**CHANGE IN APPEARANCE:** hygroscopic
**COLOR:** colorless to white
**PHYSICAL FORM:** crystalline powder
**ODOR:** odorless
**MAJOR HEALTH HAZARDS:** eye irritation

**POTENTIAL HEALTH EFFECTS:**
**INHALATION:**
**SHORT TERM EXPOSURE:** irritation, cough, sore throat
**LONG TERM EXPOSURE:** no information is available
**SKIN CONTACT:**
**SHORT TERM EXPOSURE:** irritation
**LONG TERM EXPOSURE:** irritation
**EYE CONTACT:**
**SHORT TERM EXPOSURE:** irritation
**LONG TERM EXPOSURE:** irritation
**INGESTION:**
**SHORT TERM EXPOSURE:** gastrointestinal irritation, fever, nausea, vomiting, diarrhea, loss of appetite, disorientation, lung congestion, effects on the brain, convulsions, coma
**LONG TERM EXPOSURE:** changes in blood pressure

**CARCINOGEN STATUS:**
**OSHA:** No
**NTP:** No
**IARC:** No

## 4. FIRST AID MEASURES

**INHALATION:** If adverse effects occur, remove to uncontaminated area. Give artificial respiration if not breathing. Get immediate medical attention.

**SKIN CONTACT:** Wash skin with soap and water for at least 15 minutes while removing contaminated clothing and shoes. Get medical attention, if needed. Thoroughly clean and dry contaminated clothing and shoes before reuse.

**EYE CONTACT:** Flush eyes with plenty of water for at least 15 minutes. Then get immediate medical attention.

**INGESTION:** If a large amount is swallowed, get medical attention.

## 5. FIRE FIGHTING MEASURES

**FIRE AND EXPLOSION HAZARDS:** Negligible fire hazard.

**EXTINGUISHING MEDIA:** Use extinguishing agents appropriate for surrounding fire.

**FIRE FIGHTING:** Move container from fire area if it can be done without risk. Avoid inhalation of material or combustion by-products. Stay upwind and keep out of low areas.

## 6. ACCIDENTAL RELEASE MEASURES

**OCCUPATIONAL RELEASE:**
Collect spilled material in appropriate container for disposal.

## 7. HANDLING AND STORAGE

**STORAGE:** Store and handle in accordance with all current regulations and standards. Store in a tightly closed container. Keep separated from incompatible substances.

**HANDLING:** Use methods to minimize dust.

## 8. EXPOSURE CONTROLS, PERSONAL PROTECTION

**EXPOSURE LIMITS:**
**SODIUM CHLORIDE:**
No occupational exposure limits established.

**VENTILATION:** Provide local exhaust ventilation system. Ensure compliance with applicable exposure limits.

**EYE PROTECTION:** Wear splash resistant safety goggles with a faceshield. Provide an emergency eye wash fountain and quick drench shower in the immediate work area.

**CLOTHING:** Wear appropriate chemical resistant clothing.

**GLOVES:** Wear appropriate chemical resistant gloves.

**RESPIRATOR:** Under conditions of frequent use or heavy exposure, respiratory protection may be needed. Respiratory protection is ranked in order from minimum to maximum. Consider warning properties before use.
Any dust, mist, and fume respirator.
Any air-purifying respirator with a high-efficiency particulate filter.
Any powered, air-purifying respirator with a dust, mist, and fume filter.
Any powered, air-purifying respirator with a high-efficiency particulate filter.
**For Unknown Concentrations or Immediately Dangerous to Life or Health -**
Any supplied-air respirator with full facepiece and operated in a pressure-demand or other positive-pressure mode in combination with a separate escape supply.
Any self-contained breathing apparatus with a full facepiece.

## 9. PHYSICAL AND CHEMICAL PROPERTIES

**PHYSICAL STATE:** solid
**COLOR:** colorless to white
**CHANGE IN APPEARANCE:** hygroscopic
**PHYSICAL FORM:** crystalline powder
**ODOR:** odorless
**MOLECULAR WEIGHT:** 58.44
**MOLECULAR FORMULA:** Na-Cl
**BOILING POINT:** 2575 F (1413 C)
**MELTING POINT:** 1474 F (801 C)
**VAPOR PRESSURE:** 1 mmHg @ 865 C
**VAPOR DENSITY:** Not applicable
**SPECIFIC GRAVITY:** Not available

**DENSITY:** 2.165 g/cc
**WATER SOLUBILITY:** 35.7% @ 0 C
**PH:** 5.5-8.5 (5% solution)
**VOLATILITY:** Not applicable
**ODOR THRESHOLD:** Not available
**EVAPORATION RATE:** Not applicable
**COEFFICIENT OF WATER/OIL DISTRIBUTION:** Not available
**SOLVENT SOLUBILITY:**
**Soluble:** glycerol
**Slightly Soluble:** alcohol, liquid ammonia
**Insoluble:** hydrochloric acid

## 10. STABILITY AND REACTIVITY

**REACTIVITY:** Stable at normal temperatures and pressure.

**CONDITIONS TO AVOID:** None reported.

**INCOMPATIBILITIES:** metals, combustible materials, halogenated compounds

SODIUM CHLORIDE:
BROMINE TRIFLUORIDE: Possible violent reaction.
BUILDING MATERIALS: May be attacked.
DICHLOROMALEIC ANHYDRIDE + UREA: Explosive reaction above 118 C.
LITHIUM (BURNING): Releases violently flammable sodium.
METALS: May be attacked.
NITROGEN COMPOUNDS: May form explosive compounds under electrolysis conditions.

**HAZARDOUS DECOMPOSITION:**
Thermal decomposition products: halogenated compounds, oxides of sodium

**POLYMERIZATION:** Will not polymerize.

## 11. TOXICOLOGICAL INFORMATION

**SODIUM CHLORIDE:**
**IRRITATION DATA:**
50 mg/24 hour(s) skin-rabbit mild; 500 mg/24 hour(s) skin-rabbit mild; 100 mg eyes-rabbit mild; 100 mg/24 hour(s) eyes-rabbit moderate; 10 mg eyes-rabbit moderate
**TOXICITY DATA:**
12357 mg/kg/23 day(s) continuous oral-human TDLo; 1 gm/kg oral-man LDLo; >42 gm/m3/1 hour(s) inhalation-rat LC50; 3500 mg/kg subcutaneous-rat LDLo; 4 gm/kg oral-mouse LD50; 2602 mg/kg intraperitoneal-mouse LD50; 3 gm/kg subcutaneous-mouse LD50; 645 mg/kg intravenous-mouse LD50; 131 mg/kg intracervical-mouse LD50; 2 gm/kg intravenous-dog LDLo; 8 gm/kg oral-rabbit LDLo; >10 gm/kg skin-rabbit LD50; 1100 mg/kg intravenous-rabbit LDLo; 2160 mg/kg subcutaneous-guinea pig LDLo; 300 mg/kg intravenous-guinea pig LDLo; 300 mg/kg parenteral-guinea pig LDLo; 300 mg/kg intraarterial-guinea pig LDLo; 3000 mg/kg oral-rat LD50; 2600 mg/kg intraperitoneal-rat LD50; 1 mg/kg/24 hour(s) oral-rat TDLo; 3.72 gm/kg intraperitoneal-rat LDLo; 375 mg/kg intravenous-dog

TDLo; 16800 mg/kg/28 day(s) continuous oral-rat TDLo; 37500 mg/kg/30 day(s) continuous oral-rat TDLo; 12500 mg/kg/10 day(s) continuous oral-rat TDLo

**LOCAL EFFECTS:**

Irritant: eye

**ACUTE TOXICITY LEVEL:**

Moderately Toxic: ingestion

**MUTAGENIC DATA:**

other mutation test systems - Escherichia coli 150 mmol/L; mutation in microorganisms - Saccharomyes cerevisae 2 mol/L (-S9); DNA inhibition - human fibroblast 125 mmol/L; unscheduled DNA synthesis - rat oral 16800 mg/kg 4 week(s)-continuous; other mutation test systems - rat oral 400 mg/kg; cytogenetic analysis - rat intraperitoneal 2338 mg/kg; DNA damage - mouse lymphocyte 101 mmol/L; mutation in mammalian somatic cells - mouse lymphocyte 57200 umol/L; micronucleus test - hamster lung 4 gm/L; DNA damage - hamster ovary 275 mmol/L; cytogenetic analysis - hamster ovary 160 mmol/L; cytogenetic analysis - hamster lung 7500 mg/L; micronucleus test - rat oral 2 pph 14 day(s)

**REPRODUCTIVE EFFECTS DATA:**

27 mg/kg intraplacental-woman TDLo 15 week(s) pregnant female continuous; 145 gm/kg oral-rat TDLo 7 day(s) pre pregnancy/1-22 day(s) pregnant female continuous; 56400 mg/kg oral-rat TDLo 5 day(s) pre pregnancy/21 day(s) post pregnancy continuous; 1710 mg/kg intraperitoneal-rat TDLo 13 day (s) pregnant female continuous; 10 gm/kg intraperitoneal-rat TDLo 17-20 day(s) pregnant female continuous; 10 mg/kg parenteral-rat TDLo 1 day(s) pre pregnancy continuous; 500 mg/kg intrauterine-rat TDLo 4 day(s) pregnant female continuous; 50 mg/kg intrauterine-rat TDLo 6 day(s) pregnant female continuous; 1900 mg/kg subcutaneous-mouse TDLo 11 day(s) pregnant female continuous; 1900 mg/kg subcutaneous-mouse TDLo 10 day(s) pregnant female continuous; 2500 mg/kg subcutaneous-mouse TDLo 10 day(s) pregnant female continuous; 13440 mg/kg subcutaneous-mouse TDLo 2-6 day (s) pregnant female continuous; 6 gm/kg intrauterine-monkey TDLo 18 week(s) pregnant female continuous; 480 mg/kg intraplacental-horse, donkey TDLo 45 day(s) pregnant female continuous

**HEALTH EFFECTS:**

**INHALATION:**

**ACUTE EXPOSURE:**

SODIUM CHLORIDE: Inhalation of dust may leave a salty taste and cause irritation to the nose and throat. Symptoms may include coughing, dryness, and sore throat.

**CHRONIC EXPOSURE:**

SODIUM CHLORIDE: No data available.

**SKIN CONTACT:**

**ACUTE EXPOSURE:**

SODIUM CHLORIDE: May cause mild irritation unless the contact is intensive which may result in dermatitis.

**CHRONIC EXPOSURE:**

SODIUM CHLORIDE: Primary irritant dermatitis may result from sodium chloride being trapped between the skin and jewelry since some metal alloys may be corroded and discolored by such contact.

**EYE CONTACT:**

**ACUTE EXPOSURE:**

SODIUM CHLORIDE: Solid particles or hypertonic solutions may cause redness, pain, irritation and a stinging sensation on contact. Solutions more dilute than 0.9% sodium chloride cause increased permeability of the corneal epithelium.

**CHRONIC EXPOSURE:**
SODIUM CHLORIDE: Repeated and prolonged contact with irritants may cause conjunctivitis.

**INGESTION:**
**ACUTE EXPOSURE:**
SODIUM CHLORIDE: Ingestion of very large doses of hypertonic solutions may cause dryness of mucous membranes and a violent inflammatory reaction in the gastrointestinal tract; ulceration may occur. Symptoms may include nausea, vomiting, diarrhea, anorexia, thirst, fever, muscular twitching, rigidity, convulsions, hypernea and prostration. Dehydration and congestion may occur in most internal organs, particularly the meninges and brain. Central nervous system disturbances such as confusion and coma may result. Generalized and pulmonary edema are possible. Death may occur from respiratory failure secondary to an acute encephalopathy.

**CHRONIC EXPOSURE:**
SODIUM CHLORIDE: Diets high in sodium chloride may cause elevated blood pressure, especially in predisposed individuals. Reproductive effects have been reported in animals.

## 12. ECOLOGICAL INFORMATION

**ECOTOXICITY DATA:**
**FISH TOXICITY:** 40000 ug/L 96 hour(s) LC50 (Mortality) Goldfish (Carassius auratus)

**INVERTEBRATE TOXICITY:** 402600 ug/L 48 hour(s) EC50 (Immobilization) Water flea (Daphnia magna)

**ALGAL TOXICITY:** 1000000 ug/L 35 week(s) (Population Growth) Blue-green algae (Anacystis nidulans)

**PHYTOTOXICITY:** 50000 ug/L 21 hour(s) (Enzyme) Pondweed (Potamogeton alpinus)

**OTHER TOXICITY:** 400000 ug/L 6 hour(s) (Mortality) Frog (Rana breviceps)

## 13. DISPOSAL CONSIDERATIONS

Dispose in accordance with all applicable regulations.

## 14. TRANSPORT INFORMATION

**U.S. DEPARTMENT OF TRANSPORTATION:** No classification assigned.

**CANADIAN TRANSPORTATION OF DANGEROUS GOODS:** No classification assigned.

**LAND TRANSPORT ADR:** No classification assigned.

**LAND TRANSPORT RID:** No classification assigned.

**AIR TRANSPORT IATA:** No classification assigned.

**AIR TRANSPORT ICAO:** No classification assigned.

**MARITIME TRANSPORT IMDG:** No classification assigned.

## 15. REGULATORY INFORMATION

**U.S. REGULATIONS:**
**CERCLA SECTIONS 102a/103 HAZARDOUS SUBSTANCES (40 CFR 302.4):** Not regulated.

**SARA TITLE III SECTION 302 EXTREMELY HAZARDOUS SUBSTANCES (40 CFR 355.30):** Not regulated.

**SARA TITLE III SECTION 304 EXTREMELY HAZARDOUS SUBSTANCES (40 CFR 355.40):** Not regulated.

**SARA TITLE III SARA SECTIONS 311/312 HAZARDOUS CATEGORIES (40 CFR 370.21):**
ACUTE: Yes
CHRONIC: No
FIRE: No
REACTIVE: No
SUDDEN RELEASE: No

**SARA TITLE III SECTION 313 (40 CFR 372.65):** Not regulated.

**OSHA PROCESS SAFETY (29CFR1910.119):** Not regulated.

**STATE REGULATIONS:**
**California Proposition 65:** Not regulated.

**CANADIAN REGULATIONS:**
**WHMIS CLASSIFICATION:** Not determined.

**EUROPEAN REGULATIONS:**
**EC CLASSIFICATION (CALCULATED):**

| | |
|---|---|
| Xi | Irritant |

**DANGER/HAZARD SYMBOL:**

**Xi**

**EC RISK AND SAFETY PHRASES:**

| | |
|---|---|
| R 36 | Irritating to eyes. |
| S 2 | Keep out of the reach of children. |
| S 24 | Avoid contact with skin. |
| S 25 | Avoid contact with eyes. |
| | |

ORIGINAL

| | |
|---|---|
| S 26 | In case of contact with eyes, rinse immediately with plenty of water and seek medical advice. |
| S 46 | If swallowed, seek medical advice immediately and show this container or label. |

**GERMAN REGULATIONS:**
**WATER HAZARD CLASS (WGK):**
**STATE OF CLASSIFICATION:** VwVwS
**CLASSIFICATION UNDER HAZARD TO WATER:** 0

**NATIONAL INVENTORY STATUS:**
**U.S. INVENTORY (TSCA):** Listed on inventory.

**TSCA 12(b) EXPORT NOTIFICATION:** Not listed.

## 16. OTHER INFORMATION

**MSDS SUMMARY OF CHANGES**
1. CHEMICAL PRODUCT AND COMPANY IDENTIFICATION
2. COMPOSITION, INFORMATION ON INGREDIENTS
3. HAZARDS IDENTIFICATION
4. FIRST AID MEASURES
6. ACCIDENTAL RELEASE MEASURES
7. HANDLING AND STORAGE
8. EXPOSURE CONTROLS, PERSONAL PROTECTION
9. PHYSICAL AND CHEMICAL PROPERTIES
10. STABILITY AND REACTIVITY
15. REGULATORY INFORMATION

ORIGINAL

# MATERIAL SAFETY DATA SHEET

## 1. CHEMICAL PRODUCT AND COMPANY IDENTIFICATION

**MDL INFORMATION SYSTEMS, INC.**
**1281 Murfreesboro Road, Suite 300**
**Nashville, TN 37217-2423**

**1-615-366-2000**

**EMERGENCY TELEPHONE NUMBER**
**1-800-424-9300 (NORTH AMERICA)**
**1-703-527-3887 (INTERNATIONAL)**

**SUBSTANCE: PENICILLIN G BENZATHINE**

**TRADE NAMES/SYNONYMS:**
4-THIA-1-AZABICYCLO(3.2.0)HEPTANE-2-CARBOXYLIC ACID, 3,3-DIMETHYL-7- OXO-6-((PHENYLACETYL)AMINO)-(2S-(2ALPHA,5ALPHA,6BETA))-, COMPD. WITH N,N'-BIS (PHENYLMETHYL)-1,2-ETHANEDIAMINE (2:1); 4-THIA-1-AZABICYCLO(3.2.0)HEPTANE-2-CARBOXYLIC ACID, 3,3 DIMETHYL-7- OXO-6-(2-PHENYLACETAMIDO)-, COMPD. WITH N,N'-DIBENZYLETHYLENEDIAMINE (2:1); (2S-(2ALPHA,5ALPHA,6BETA))-4-THIA-1-AZABICYCLO(3.2.0)HEPTANE-2-CARBOX- YLIC ACID, 3,3-DIMETHYL-7-OXO-6-((PHENYLACETYL)AMINO)-, COMPD. WITH N,N'-BIS(PHENYLMETHYL)-1,2-ETHANEDIAMINE (2:1); 3,3-DIMETHYL-7-OXO-6-(2-PHENYLACETAMIDO)-4-THIA-1-AZABICYCLO(3.2.0) HEPTANE-2-CARBOXYLIC ACID, COMPD. WITH N,N'-DIBENZYLETHYLENEDIAMINE (2:1); PENICILLIN G, N,N'-DIBENZYLETHYLENEDIAMINE SALT; BENZATHINE BENZYLPENICILLIN; BENZATHINE PENICILLIN G; DIAMINE PENICILLIN; DIBENCILLIN; PENDITAN; BICILLIN; C48H56N6O8S2; OHS18067; RTECS XH9425000

**CHEMICAL FAMILY:** antibiotic/antiseptic

**CREATION DATE:** Jul 30 1990
**REVISION DATE:** Jun 16 2005

## 2. COMPOSITION, INFORMATION ON INGREDIENTS

**COMPONENT:** PENICILLIN G BENZATHINE
**CAS NUMBER:** 1538-09-6
**EC NUMBER (EINECS):** 216-260-5
**PERCENTAGE:** 100.0

## 3. HAZARDS IDENTIFICATION

ORIGINAL

**NFPA RATINGS (SCALE 0-4):** HEALTH=1 FIRE=1 REACTIVITY=0


**EMERGENCY OVERVIEW:**
**COLOR:** colorless or white
**PHYSICAL FORM:** crystalline powder
**ODOR:** odorless
**MAJOR HEALTH HAZARDS:** allergic reactions
**PHYSICAL HAZARDS:** Dust/air mixtures may ignite or explode.

**POTENTIAL HEALTH EFFECTS:**
**INHALATION:**
**SHORT TERM EXPOSURE:** allergic reactions, asthma
**LONG TERM EXPOSURE:** no information on significant adverse effects
**SKIN CONTACT:**
**SHORT TERM EXPOSURE:** irritation, allergic reactions, asthma
**LONG TERM EXPOSURE:** same as effects reported in short term exposure
**EYE CONTACT:**
**SHORT TERM EXPOSURE:** irritation, allergic reactions
**LONG TERM EXPOSURE:** no information on significant adverse effects
**INGESTION:**
**SHORT TERM EXPOSURE:** allergic reactions
**LONG TERM EXPOSURE:** rash, nausea, vomiting, diarrhea, stomach pain, chest pain, wheezing, asthma, dizziness, bluish skin color, lung congestion, blood disorders, convulsions

**CARCINOGEN STATUS:**
**OSHA:** No
**NTP:** No
**IARC:** No

## 4. FIRST AID MEASURES

**INHALATION:** If adverse effects occur, remove to uncontaminated area. Give artificial respiration if not breathing. Get immediate medical attention.

**SKIN CONTACT:** Wash skin with soap and water for at least 15 minutes while removing contaminated clothing and shoes. Get medical attention, if needed. Thoroughly clean and dry contaminated clothing and shoes before reuse.

**EYE CONTACT:** Flush eyes with plenty of water for at least 15 minutes. Then get immediate medical attention.

**INGESTION:** If swallowed, drink plenty of water, do NOT induce vomiting. Get immediate medical attention. Induce vomiting only at the instructions of a physician. Do not give anything by mouth to unconscious or convulsive person.

**ANTIDOTE:** penicillinase. For anaphylactic reactions, epinephrine; steroids, intravenous.

**NOTE TO PHYSICIAN:** For ingestion, consider gastric lavage, activated charcoal slurry and catharsis.

## 5. FIRE FIGHTING MEASURES

**FIRE AND EXPLOSION HAZARDS:** Slight fire hazard. Dust/air mixtures may ignite or explode.

**EXTINGUISHING MEDIA:** regular dry chemical, carbon dioxide, water, regular foam

Large fires: Use regular foam or flood with fine water spray.

**FIRE FIGHTING:** Move container from fire area if it can be done without risk. Do not scatter spilled material with high-pressure water streams. Dike for later disposal. Use extinguishing agents appropriate for surrounding fire. Avoid inhalation of material or combustion by-products. Stay upwind and keep out of low areas.

## 6. ACCIDENTAL RELEASE MEASURES

**OCCUPATIONAL RELEASE:**
Collect spilled material in appropriate container for disposal. Keep out of water supplies and sewers. Keep unnecessary people away, isolate hazard area and deny entry.

## 7. HANDLING AND STORAGE

**STORAGE:** Store and handle in accordance with all current regulations and standards. Keep separated from incompatible substances. Store in a tightly closed container.

## 8. EXPOSURE CONTROLS, PERSONAL PROTECTION

**EXPOSURE LIMITS:**
**PENICILLIN G BENZATHINE:**
No occupational exposure limits established.

**VENTILATION:** Provide local exhaust ventilation system. Ensure compliance with applicable exposure limits.

**EYE PROTECTION:** Wear splash resistant safety goggles with a faceshield. Provide an emergency eye wash fountain and quick drench shower in the immediate work area.

**CLOTHING:** Wear appropriate chemical resistant clothing.

**GLOVES:** Wear appropriate chemical resistant gloves.

**RESPIRATOR:** Under conditions of frequent use or heavy exposure, respiratory protection may be needed. Respiratory protection is ranked in order from minimum to maximum. Consider warning properties before use.
Any supplied-air respirator with a full facepiece that is operated in a pressure-demand or other positive-pressure mode.
Any self-contained breathing apparatus that has a full facepiece and is operated in a pressure-demand or other positive-pressure mode.
**For Unknown Concentrations or Immediately Dangerous to Life or Health -**

Any supplied-air respirator with full facepiece and operated in a pressure-demand or other positive-pressure mode in combination with a separate escape supply.
Any self-contained breathing apparatus with a full facepiece.

## 9. PHYSICAL AND CHEMICAL PROPERTIES

**PHYSICAL STATE:** solid
**COLOR:** colorless or white
**PHYSICAL FORM:** crystalline powder
**ODOR:** odorless
**TASTE:** tasteless
**MOLECULAR WEIGHT:** 909.22
**MOLECULAR FORMULA:** C32-H36-N4-O8-S2.C16-H20-N2
**BOILING POINT:** Not applicable
**MELTING POINT:** 253-255 F (123-124 C)
**VAPOR PRESSURE:** Not applicable
**VAPOR DENSITY:** Not applicable
**SPECIFIC GRAVITY:** Not available
**WATER SOLUBILITY:** very slightly soluble
**PH:** 4.7-7.5
**VOLATILITY:** Not applicable
**ODOR THRESHOLD:** Not available
**EVAPORATION RATE:** Not applicable
**COEFFICIENT OF WATER/OIL DISTRIBUTION:** Not available
**SOLVENT SOLUBILITY:**
**Soluble:** benzene
**Moderately Soluble:** formamide
**Slightly Soluble:** alcohol, acetone

## 10. STABILITY AND REACTIVITY

**REACTIVITY:** Stable at normal temperatures and pressure.

**CONDITIONS TO AVOID:** Avoid heat, flames, sparks and other sources of ignition. Avoid contact with incompatible materials.

**INCOMPATIBILITIES:** oxidizing materials

PENICILLIN G BENZATHINE:
OXIDIZERS (STRONG): Fire and explosion hazard.

**HAZARDOUS DECOMPOSITION:**
Thermal decomposition products: oxides of carbon, nitrogen, sulfur

**POLYMERIZATION:** Will not polymerize.

## 11. TOXICOLOGICAL INFORMATION

**PENICILLIN G BENZATHINE:**
**TOXICITY DATA:**
2 gm/kg oral-mouse LD50; 460 mg/kg intraperitoneal-mouse LD50
**ACUTE TOXICITY LEVEL:**
Moderately Toxic: ingestion
**TARGET ORGANS:** immune system (sensitizer)
**MEDICAL CONDITIONS AGGRAVATED BY EXPOSURE:** immune system disorders or allergies
**REPRODUCTIVE EFFECTS DATA:**
22905 ug/kg parenteral-rat TDLo 4 day(s) pregnant female continuous
**ADDITIONAL DATA:** May cross the placenta. May be excreted in breast milk. Interactions with drugs may occur. May cross react with similar compounds.

**HEALTH EFFECTS:**
**INHALATION:**
PENICILLIN G BENZATHINE: See information on penicillins. In addition, irritation of the respiratory tract has been reported.

**ACUTE EXPOSURE:**
PENICILLINS: On rare occasions, anaphylactic shock, as detailed in ingestion, has resulted from the inhalation of penicillins in sensitive individuals. Bronchoconstriction and asthma may occur.

**CHRONIC EXPOSURE:**
PENICILLINS: Repeated exposure may result in sensitization.

**SKIN CONTACT:**
PENICILLIN G BENZATHINE: See information on penicillins. In addition, irritation has been reported.

**ACUTE EXPOSURE:**
PENICILLINS: Topical administration of penicillins has produced serious hypersensitivity reactions such as angioedema with marked swelling of the lips, tongue, face and periorbital tissues, asthmatic breathing and giant hives. Intradermal instillation of very small quantities in skin testing has resulted in anaphylaxis and death in sensitized individuals.

**CHRONIC EXPOSURE:**
PENICILLINS: Repeated contact may result in sensitization. Allergic contact dermatitis has been reported from handling penicillins or the repeated topical application of penicillin ointments.

**EYE CONTACT:**
PENICILLIN G BENZATHINE: See information on penicillins. In addition, irritation has been reported.

**ACUTE EXPOSURE:**
PENICILLINS: The penicillins have had a high incidence of contact allergic reactions when applied topically.

**CHRONIC EXPOSURE:**
PENICILLINS: Repeated contact may result in sensitization and polyarthralgia ecchymosis.

**INGESTION:**
PENICILLIN G BENZATHINE: See information on penicillins.

**ACUTE EXPOSURE:**
PENICILLINS: In non-allergic persons, even large doses are generally non-toxic. Hypersensitivity reactions, immediate and/or delayed, may occur in individuals without known prior exposure and may be due to unrecognized exposure to penicillin in the environment. These reactions may include anaphylaxis, angioedema and serum sickness type reactions; symptoms are described in chronic exposure.

**CHRONIC EXPOSURE:**
PENICILLINS: Repeated ingestion of penicillins may cause nausea with or without vomiting, epigastric distress, mild to severe diarrhea, sore or dry mouth, sore or black hairy tongue. Pseudomembranous colitis has been reported rarely. The most severe immediate hypersensitivity reaction is anaphylactic shock, which although usually associated with parenteral administration, has occurred with ingestion. Symptoms, which can occur within minutes, may include urticaria, purpuric skin lesions, localized edema, extreme weakness, dizziness, nausea, vomiting, diarrhea, abdominal pain and cramps, bronchoconstriction with severe asthma, chest pain, severe hypotension, cyanosis, circulatory collapse, pulmonary edema, convulsions and death in respiratory failure. Some individuals may have angioedema with marked swelling of the lips, tongue, face and periorbital tissues, asthmatic breathing and giant hives. Other immediate reactions may include laryngeal edema, laryngospasm and bronchospasm. Delayed reactions may include various skin rashes, ranging from maculopapular to exfoliative dermatitis, and serum sickness type reactions. Symptoms of the latter may include chills with or without fever, rash, leukopenia, purpura, arthralgia or arthritis, myalgia, generalized edema, malaise, mental changes, lymphadenopathy, splenomegaly, ECG changes indicative of myocarditis and albuminuria and hematuria. Interstitial nephritis has been reported. Other signs of hypersensitivity may include wheezing, flushing of the skin, pruritus, vasculitis of the skin or other organs, positive coomb's reactions, infrequently with hemolytic anemia, neutropenia, thrombocytopenia, eosinophilia, granulocytopenia and anemia. Infrequent effects may include jaundice, liver necrosis, central nervous system toxicity and neuropathy.

## 12. ECOLOGICAL INFORMATION

Not available

## 13. DISPOSAL CONSIDERATIONS

Dispose in accordance with all applicable regulations.

## 14. TRANSPORT INFORMATION

**U.S. DEPARTMENT OF TRANSPORTATION:** No classification assigned.

**CANADIAN TRANSPORTATION OF DANGEROUS GOODS:** No classification assigned.

**LAND TRANSPORT ADR:** No classification assigned.

**LAND TRANSPORT RID:** No classification assigned.

**AIR TRANSPORT IATA:** No classification assigned.

ORIGINAL

**AIR TRANSPORT ICAO:** No classification assigned.

**MARITIME TRANSPORT IMDG:** No classification assigned.

## 15. REGULATORY INFORMATION

**U.S. REGULATIONS:**
**CERCLA SECTIONS 102a/103 HAZARDOUS SUBSTANCES (40 CFR 302.4):** Not regulated.

**SARA TITLE III SECTION 302 EXTREMELY HAZARDOUS SUBSTANCES (40 CFR 355.30):**
Not regulated.

**SARA TITLE III SECTION 304 EXTREMELY HAZARDOUS SUBSTANCES (40 CFR 355.40):**
Not regulated.

**SARA TITLE III SARA SECTIONS 311/312 HAZARDOUS CATEGORIES (40 CFR 370.21):**
ACUTE: Yes
CHRONIC: Yes
FIRE: No
REACTIVE: No
SUDDEN RELEASE: No

**SARA TITLE III SECTION 313 (40 CFR 372.65):** Not regulated.

**OSHA PROCESS SAFETY (29CFR1910.119):** Not regulated.

**STATE REGULATIONS:**
**California Proposition 65:** Not regulated.

**CANADIAN REGULATIONS:**
**WHMIS CLASSIFICATION:** Not determined.

**EUROPEAN REGULATIONS:**
**EC CLASSIFICATION (CALCULATED):**

| | |
|---|---|
| Xn | Harmful |

**DANGER/HAZARD SYMBOL:**

**Xn**

**EC RISK AND SAFETY PHRASES:**

| | |
|---|---|
| R 42 | May cause sensitization by inhalation. |
| R 43 | May cause sensitization by skin contact. |
| R 64 | May cause harm to breastfed babies. |
| S 2 | Keep out of the reach of children. |

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| | |
|---|---|
| S 24 | Avoid contact with skin. |
| S 46 | If swallowed, seek medical advice immediately and show this container or label. |

**NATIONAL INVENTORY STATUS:**
**U.S. INVENTORY (TSCA):** Listed on inventory.

**TSCA 12(b) EXPORT NOTIFICATION:** Not listed.

## 16. OTHER INFORMATION

**MSDS SUMMARY OF CHANGES**
15. REGULATORY INFORMATION

INVOICE #: 112614 CUST. #: 6135 CUSTOMER: WYETH LABORATORIES, INC.


Codeine Phosphate
Common Name
Cat # 14400
Units package size: 100 mg

ORIGINAL

# MATERIAL SAFETY DATA SHEET
## UNITED STATES PHARMACOPEIAL CONVENTION, INC.

address:
12601 Twinbrook Parkway
Rockville, MD 20852 USA

emergency and information
telephone calls:
(301) 881-0666

William M. Heller
Responsible Party

12-31-85
date prepared

WARNING STATEMENT
WARNING! REFERENCE STANDARD; NOT FOR HUMAN CONSUMPTION; AVOID INGESTION, INHALATION, SKIN CONTACT. FOR CHEMICAL TEST AND ASSAY USE ONLY.

## SECTION 1 - IDENTITY

| | |
|---|---|
| COMMON NAME | Codeine Phosphate |
| SYNONYMS | Methylmorphine Phosphate |
| CAS NUMBER | 41444-62-6 (hemihydrate), 52-28-8 (anhydrous) |
| RTEC NUMBER | QD1310000 (anhydrous) |
| CHEMICAL NAME | 7,8-Didehydro-4,5a-epoxy-3-methoxy-17-methylmorphinan-6a-ol phosphate (1:1)(salt) hemihydrate |
| CHEMICAL FAMILY | Antitussive, narcotic analgesic |
| FORMULA | C18H21NO3. H3PO4. 1/2 H2O |

## SECTION 2 - HAZARDOUS INGREDIENTS

| | NAME | PERCENT | THRESHOLD LIMIT VALUE (UNITS) |
|---|---|---|---|
| PRINCIPAL HAZARDOUS COMPONENT(S)/[Chemical & Common name(s)] | Codeine Phosphate | Pure Material | Not Established |

## SECTION 3 - PHYSICAL AND CHEMICAL CHARACTERISTICS (Fire & Explosion Data)

| | |
|---|---|
| BOILING POINT | n/a |
| SPECIFIC GRAVITY (H2O = 1) | n/a |
| VAPOR PRESSURE (mm Hg) | n/a |

n/a = not applicable

Codeine Phosphate
Common Name
Cat # 14400

ORIGINAL

MATERIAL SAFETY DATA SHEET
UNITED STATES PHARMACOPEIAL CONVENTION, INC.

| | |
|---|---|
| PERCENT VOLATILE BY VOLUME (%) | n/a |
| VAPOR DENSITY (AIR = 1) | n/a |
| EVAPORATION RATE | n/a |
| SOLUBILITY IN WATER | Soluble |
| REACTIVITY IN WATER | n/a |
| APPEARANCE AND ODOR | Small colorless crystals or white crystalline powder, odorless |
| FLASH POINT | n/a |
| FLAMMABLE LIMITS IN AIR % BY VOLUME | LOWER n/a UPPER n/a |
| EXTINGUISHER MEDIA | Water spray, dry chemical, carbon dioxide or foam as appropriate for surrounding fire and materials. |
| AUTO-IGNITION TEMPERATURE | n/a |
| SPECIAL FIRE FIGHTING PROCEDURES | As with all fires, evacuate personnel to safe area. Firefighters should use self-contained breathing equipment and protective clothing. |
| UNUSUAL FIRE AND EXPLOSION HAZARDS | This material is assumed to be combustible. As with all dry powders it is advisable to ground mechanical equipment in contact with dry material to dissipate the potential buildup of static electricity. When heated to decomposition material emits toxic fumes. Emits toxic fumes under fire conditions. |

## SECTION 4 - PHYSICAL HAZARDS

| | |
|---|---|
| STABILITY | ( ) Unstable ( X ) Stable |
| CONDITIONS TO AVOID | Material is stable from a safety point of view. Material is affected by light. |
| INCOMPATABILITY (MATERIALS TO AVOID) | n/a |
| HAZARDOUS DECOMPOSITION PRODUCTS | When heated to decomposition material emits toxic fumes. Emits toxic fumes under fire conditions. |
| HAZARDOUS POLYMERIZATION | ( ) May Occur ( X ) Will Not Occur |

n/a = not applicable

Codeine Phosphate
Common Name
Cat # 14400

ORIGINAL

MATERIAL SAFETY DATA SHEET
UNITED STATES PHARMACOPEIAL CONVENTION, INC.

## SECTION 5 - HEALTH HAZARDS

**THRESHOLD LIMIT VALUE** None established

**SIGNS AND SYMPTOMS OF OVEREXPOSURE**

[LD50: 1178 mg/kg oral-rat;
LD50: 365 mg/kg subcutaneous-rat;
LD50: 208 mg/kg intramuscular-rat;
LD50: 290 mg/kg oral-mouse;
LD50: 110 mg/kg intraperitoneal-mouse;
LD50: 191 mg/kg subcutaneous-mouse;
LD50: 70 mg/kg intravenous-mouse;
LD50: 191 mg/kg intramuscular-mouse;
LD50: 98 mg/kg intravenous-dog;
LD50: 352 mg/kg intraperitoneal-guinea pig;
LD50: 153 mg/kg subcutaneous-mouse] The lethal dose for a non-addicted person is about 0.5 to 1.0 grams. Deaths from codeine overdose are relatively rare. Common adverse reactions are nausea, vomiting, constipation, dizziness, palpitations, drowsiness and pruritis. As with other narcotics, overdoses produce central nervous system depression, respiratory depression, pinpoint pupils and coma. Body temperature and blood pressure may fall. Possible allergic reaction to dust if inhaled, ingested or in contact with skin.

**ACUTE** Eye, skin and/or respiratory tract irritation

**CHRONIC** Possible hypersensitization

**PRECAUTIONS TO CONSIDER** Persons developing hypersensitivity (anaphylactic) reactions must receive immediate medical attention. Material may be irritating to mucous membranes and respiratory tract. As a general rule, when handling USP Reference Standards avoid all contact and inhalation of dust, fumes, mists, and/or vapors associated with the material. Keep container tightly closed and use with adequate ventilation; wash thoroughly after handling. Individuals working with chemicals should consider all chemicals to be potentially hazardous even if their individual hazards may be uncharacterized or unknown. Codeine is a narcotic component and can produce drug dependence of the morphine type and therefore has the potential for abuse.

---

= not applicable

Codeine Phosphate
Common Name
Cat # 14400

MATERIAL SAFETY DATA SHEET
UNITED STATES PHARMACOPEIAL CONVENTION, INC.

ORIGINAL

MEDICAL CONDITIONS
AGGRAVATED BY EXPOSURE Hypersensitivity to material

| | | | |
|---|---|---|---|
| CHEMICAL LISTED AS | NATIONAL TOXICOLOGY PROGRAM | ( ) Yes | ( X ) No |
| CARCINOGEN OR POTENTIAL | I.A.R.C. Monographs | ( ) Yes | ( X ) No |
| CARCINOGEN | OSHA | ( ) Yes | ( X ) No |
| | OTHER | | n/a |

ACGIH TLV: n/a

OTHER EXPOSURE LIMIT(S) USED: n/a

OSHA PERMISSIBLE EXPOSURE LIMIT: Not established

OTHER EXPOSURE LIMIT USED Not established

EMERGENCY AND FIRST AID PROCEDURES: Remove from exposure. Remove contaminated clothing. Persons developing serious hypersensitivity reactions must receive immediate medical attention. Upon eye or skin contact, flush affected area with copious quantities of water. Obtain medical attention. Codeine is a narcotic and can produce drug dependence of the morphine type and therefore has the potential for abuse. In the presence of hypoventilation or apnea, oxygen should be administered and respiration should be maintained. The duration of respiratory depression following overdose may be longer than the duration of narcotic antagonist action. Keep the person awake, walk person around. Keep the person warm. Emetic as recommended by physician should be given.

1. INHALATION — May cause irritation of respiratory tract. Avoid inhalation. Remove to fresh air.
2. EYES — May cause irritation. Flush with copious quantities of water. Avoid contact.
3. SKIN — May cause irritation. Flush with copious quantities of water. Avoid contact.
4. INGESTION — May cause irritation. Avoid ingestion. Flush out mouth with water.

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n/a = not applicable

Codeine Phosphate
Common Name
Cat # 14400

ORIGINAL

MATERIAL SAFETY DATA SHEET
UNITED STATES PHARMACOPEIAL CONVENTION, INC.

## SECTION 6 - SPECIAL PROTECTION INFORMATION

| | |
|---|---|
| RESPIRATORY PROTECTION (SPECIFY TYPE) | NIOSH approved respirator |
| VENTILATION | Adequate |
| LOCAL EXHAUST | Recommended |
| MECHANICAL (GENERAL) | Recommended |
| OTHER | n/a |
| PROTECTIVE GLOVES | Impervious rubber |
| EYE PROTECTION | Safety goggles |
| OTHER PROTECTIVE CLOTHING OR EQUIPMENT | Protect exposed skin, use appropriate laboratory apparel |

## SECTION 7 - SPECIAL PRECAUTIONS AND SPILL/LEAK PROCEDURES

| | |
|---|---|
| PRECAUTIONS TO BE TAKEN IN HANDLING AND STORAGE | Store in tight container as defined in the United States Pharmacopeia. This material should be handled and stored per label and other instructions to ensure product integrity. |
| OTHER PRECAUTIONS | Avoid contact with eyes, skin or clothing. Avoid breathing dust or mist. Use with adequate dust control. Wash thoroughly after handling. Wear fresh clothing daily. Wash contaminated clothing before reuse. Do not permit eating, drinking or smoking near material. |
| STEPS TO BE TAKEN IN CASE MATERIAL IS SPILLED OR RELEASED | Wear approved respirator and chemically compatible gloves. Vacuum or sweep up spillage. Avoid dust. Place spillage in appropriate container for waste disposal. Wash contaminated clothing before reuse. Ventilate area and wash spill site. |
| WASTE DISPOSAL METHODS | Dispose of waste in accordance with all applicable Federal, State and local laws. |

n/a = not applicable

Codeine Phosphate
Common Name
Cat # 14400

ORIGINAL

MATERIAL SAFETY DATA SHEET
UNITED STATES PHARMACOPEIAL CONVENTION, INC.

NOTICE: The information contained herein is applicable solely to the chemical substance when used as a USP Reference Standard and does not relate to any other use of the substance described. Its use is intended by persons having technical skill and at their own discretion and risk. The information has been developed by USP staff from sources considered reliable but has not been independently verified by the USP. Therefore, the USP Convention cannot guarantee the accuracy of the information in these sources nor should the statements contained herein be considered an official expression. NO REPRESENTATION OR WARRANTY, EXPRESS OR IMPLIED, INCLUDING THE WARRANTIES OF MERCHANTABILITY AND FITNESS FOR A PARTICULAR PURPOSE is made with respect to the information contained herein.

ATTENTION:
This Product is Sold as a Reference Standard for Use In Chemical Analysis Not For Human Consumption.

= not applicable

8Us0s3T1L1X0G7.3Cs10H

ORIGINAL

OHS83101

# MATERIAL SAFETY DATA SHEET

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CUPATIONAL HEALTH SERVICES, INC.
WEST 42ND STREET, 12TH FLOOR
W YORK, NEW YORK 10036
800-445-MSDS (1-800-445-6737) OR
212-789-3535


FOR EMERGENCY SOURCE INFORMATION
CONTACT: 1-615-366-2000 USA

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## SUBSTANCE IDENTIFICATION

CAS NUMBER: 20830-75-5
RTECS NUMBER: IH6125000

BSTANCE: DIGOXIN

ADE NAMES/SYNONYMS:
CHLOROFORMIC DIGITALIN; CORDIOXIL; DAVOXIN; DIGACIN; DIGOSIN; DILANACIN;
DIXINA; HOMOLLE'S DIGITALIN; LANICOR; LANOCARDIN; LANOXIN; ROUGOXIN;
3-((O-2,6-DIDEOXY-BETA-D-RIBO-HEXOPYRANOSYL-(1-4)-O-2,6-DIDEOXY-BETA-
)-RIBO-HEXOPYRANOSYL-(1-4)-2,6-DIDEOXY-BETA-D-RIBO-HEXOPYRANOSYL)OXY)-
12,14-DIHYDROXY-CARD-20(22)-ENOLIDE;
)IGOXIN REFERENCE STANDARD (DUPONT); C41H64O14; OHS83101

EMICAL FAMILY:
:roid

ar

ULAR FORMULA: C41-H64-O14

ECULAR WEIGHT: 780.92

CLA RATINGS (SCALE 0-3): HEALTH=3 FIRE=1 REACTIVITY=0 PERSISTENCE=2
A RATINGS (SCALE 0-4): HEALTH=4 FIRE=1 REACTIVITY=0

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## COMPONENTS AND CONTAMINANTS

PONENT: DIGOXIN PERCENT: 100.0
CAS# 20830-75-5

ER CONTAMINANTS: NONE.

OSURE LIMITS:
OXIN:
o occupational exposure limits established by OSHA, ACGIH, or NIOSH.
0/10,000 pounds SARA Section 302 Threshold Planning Quantity
pound SARA Section 304 Reportable Quantity

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## PHYSICAL DATA

RIPTION: Clear to white crystalline solid

NG POINT: 509 F (265 C) decomposes SPECIFIC GRAVITY: not available

BILITY IN WATER: insoluble

)LVENT SOLUBILITY: Soluble in dilute alcohol and pyridine; insoluble
ı chloroform and ether.

---

## FIRE AND EXPLOSION DATA

IRE AND EXPLOSION HAZARD:
light fire hazard when exposed to heat or flame.

ıst-air mixtures may ignite or explode.

IREFIGHTING MEDIA:
ry chemical, carbon dioxide, water spray or regular foam
1993 Emergency Response Guidebook, RSPA P 5800.6).

or larger fires, use water spray, fog or regular foam
1993 Emergency Response Guidebook, RSPA P 5800.6).

IREFIGHTING:
ove container from fire area if you can do it without risk (1993 Emergency
esponse Guidebook, RSPA P 5800.6, Guide Page 53).

ctinguish using agent suitable for type of surrounding fire. Avoid breathing
apors and dusts. Keep upwind.

---

## TRANSPORTATION DATA

S. DEPARTMENT OF TRANSPORTATION SHIPPING NAME-ID NUMBER, 49 CFR 172.101:
oisonous solids, n.o.s. (digoxin)-UN 2811

S. DEPARTMENT OF TRANSPORTATION HAZARD CLASS OR DIVISION, 49 CFR 172.101:
1 - Poisonous materials

S. DEPARTMENT OF TRANSPORTATION PACKING GROUP, 49 CFR 172.101:
I

S. DEPARTMENT OF TRANSPORTATION LABELING REQUIREMENTS, 49 CFR 172.101
AND SUBPART E:
ison

S. DEPARTMENT OF TRANSPORTATION PACKAGING AUTHORIZATIONS:
CEPTIONS: None
N-BULK PACKAGING: 49 CFR 173.211
LK PACKAGING: 49 CFR 173.242

S. DEPARTMENT OF TRANSPORTATION QUANTITY LIMITATIONS 49 CFR 172.101:
SSENGER AIRCRAFT OR RAILCAR: 5 kg
RGO AIRCRAFT ONLY: 50 kg

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## TOXICITY

OXIN:
XICITY DATA: 127 ug/kg oral-child TDLo; 200 ug/kg oral-cat LD50; 300 ug/kg
oral-dog LDLo; 3500 ug/kg oral-guinea pig LD50; 17,780 ug/kg oral-mouse

LD50; 100 ug/kg oral-woman TDLo; 333 ug/kg oral-man TDLo; 200 ug/kg intravenous-infant LDLo; 25 mg/kg intravenous-rat LD50; 50 mg/kg intravenous-infant TDLo; 25 mg/kg intravenous-rat LD50; 7670 ug/kg intravenous-mouse LD50; 159 ug/kg intravenous-cat LDLo; 200 ug/kg intravenous-dog LDLo; 468 ug/kg intravenous-guinea pig LDLo; 3560 ug/kg intravenous-rabbit LD50; 230 ug/kg intravenous-pig LDLo; 124 ug/kg intracerebral-mouse LD50; 3964 ug/kg intraperitoneal-mouse LD50; 800 ug/kg intraperitoneal-guinea pig LD50; 4 mg/kg intraperitoneal-rat LD50; 630 ug/kg intramuscular-guinea pig LD50; 441 ug/kg intraduodenal-cat LDLo; 8600 ug/kg intraduodenal-guinea pig LDLo; 1580 ug/kg intraduodenal-pig LDLo; 2947 ug/kg parenteral-mouse LDLo; 5 mg/kg rectal-rat LDLo; 30 mg/kg subcutaneous-rat LD50; 12,880 ug/kg subcutaneous-mouse LD50; 600 ug/kg subcutaneous-guinea pig LD50; 13 ug/kg/4 days intermittent unreported-man TDLo; reproductive effects data (RTECS).

RCINOGEN STATUS: None.

UTE TOXICITY LEVEL: Highly toxic by ingestion.

RGET EFFECTS: Poisoning may affect the heart and central nervous system.

INCREASED RISK FROM EXPOSURE: Persons with renal insufficiency, hypothyroidism, or heart disorders.

DITIONAL DATA: Interactions with medications have been reported.

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## HEALTH EFFECTS AND FIRST AID

IALATION:

OXIN:

CUTE EXPOSURE- No data available.

HRONIC EXPOSURE- No data available.

AID- Remove from exposure area to fresh air immediately. Perform rtificial respiration if necessary. Keep person warm and at rest. Treat ymptomatically and supportively. Get medical attention immediately.

N CONTACT:

OXIN:

CUTE EXPOSURE- No data available on contact. However, skin rash may occur as a rare side effect from ingestion of digoxin.

HRONIC EXPOSURE- No data available.

ST AID- Remove contaminated clothing and shoes immediately. Wash with oap or mild detergent and large amounts of water until no evidence of hemical remains (at least 15-20 minutes). Get medical attention mmediately.

CONTACT:

OXIN:

CUTE EXPOSURE- Digoxin applied to human eyes at a concentration of 25 mg/100 mL 3 times a day caused injury of the cornea consisting of epithelial edema, swelling of the corneal stroma, and wrinkling of Descemet's membrane, all of which were reversible when the medication was discontinued.

HRONIC EXPOSURE- No data available for contact. However, systemic poisoning may occur due to ingestion. Rare visual disturbances consisting of blurred vision, photophobia, appearance of snow on objects outdoors, white borders or halos may appear on dark objects, disturbances of color vision may occur particularly causing a yellow or green appearance of objects, but less frequently red. Transitory amblyopia, diplopia and scotomata may ensue. Visual hallucinations and oculomotor paresis have

been noted with digoxin. Reduction of intraocular pressure has been produced following ingestion of large doses. However, the doses generally required have caused excessive digestive and cardiovascular side effects.

R.T AID- Wash eyes immediately with large amounts of water or normal saline, occasionally lifting upper and lower lids, until no evidence of chemical remains (at least 15-20 minutes). Get medical attention immediately.

GESTION:
GOXIN:
GHLY TOXIC.
ACUTE EXPOSURE- Ingestion of a large dose of cardiac glycosides may cause persistent nausea, salivation, vomiting, diarrhea, abdominal pain and discomfort, anorexia, marked muscular weakness, fatigue, drowsiness, headache, malaise, vertigo, increased irritability, fall in blood pressure, irregular pulse and cold extremities. Neuralgic pain involving the lower third of the face, paresthesias, aphasia, disorientation, mental depression, personality changes, defects in memory and concentration, delerium, hallucinations, visual disturbances of multiple nature and even frank psychosis may occur. Convulsions and coma are rare. Gynecomastia may be induced in men on digitalis therapy. Anemia, thrombocytopenia and eosinophilia has been reported. Hyperkalemia, oliguria and dysuria may also occur. Acute hemorrhage, necrosis of the intestine and rarely petechial hemorrhage of the myocardium have accompanied digitalis poisoning in man. Bradycardia, heart block, cardiac arrhythmias with symptoms of palpitation, hypotension and sudden death may occur. The most common arrhthmias are ventricular, coupled beats or bigeminy, extrasystoles, supraventricular, paroxysmal atrial tachycardias, ventricular fibrillation, premature beats, wenckebach phenomenon, wandering pacemaker, nonparoxysmal junctional tachycardia developing in the presence of atrial fibrillation and various forms of heart block. Mesenteric infarction from circulatory failure with low cardiac output and hypotension may occur. In infants, cardiac arrhythmias most commonly occur. In children, nodal and atrial tachycardias are common, whereas the ventricular arrhythmias are rare. Severe central nervous system depression may occur. Younger individuals without significant heart disease tend to exhibit bradycardia and heart block while others may exhibit ventricular arrhythmias with or without heart block. Elderly persons are likely to have bizzare mental symptoms. An overdosage of maternally administered digoxin has resulted in fetal toxicity and neonatal death. Cardiac glycosides cross the placental barrier and are excreted in breast milk. However, neonates are relatively resistant to their toxicity. The estimated single lethal dose is 5-25 mg. Death generally is due to ventricular fibrillation or cardiac standstill. Pathologic findings may consist of cardiac failure and pulmonary congestion.
HRONIC EXPOSURE- Symptoms from acute exposure may come on gradually if repeated or prolonged overdoses are ingested. Hypokalemia is frequently seen with chronic digitalis poisoning. The occurrence of nausea and vomiting tends to limit the amount of the cardiac glycoside ingested.

ST AID- Remove ingested drug by ipecac emesis followed by activated arcoal. Maintain respiration and determine serum potassium and gnesium levels hourly. Monitor ECG. Be prepared for transvenous cardiac cing. Do not give epinephrine or other stimulants. Get medical attention mediately (Dreisbach, Handbook of Poisoning, 12th Ed.).

NTIDOTE:
ıe following antidote has been recommended. However, the decision as to ıether the severity of poisoning requires administration of any antidote and :( al dose required should be made by qualified medical personnel.

)R CARDIAC GLYCOSIDES:
)r cardiac arrhythmias in the presence of hypokalemia, if kidney function ; normal, give potassium chloride, 5 g dissolved in fruit juice every hour :ally, or 20 meq in 500 mL of 5% dextrose slowly intravenously at a rate )t to exceed 0.4 meq/minute, until the EKG shows improvement or reveals a )tassium effect as indicated by peaking of the T wave. Administration ould be stopped when serum potassium rises to 5 meq/l. Do not use tassium in the presence of complete heart block due to digitalis. r atrial and ventricular irregularities that do not respond to potassium erepy, give phenytoin, 0.5 mg/kg slowly intravenously at 1 to 2 hour tervals. The maximum dose should not exceed 10 mg/kg/24 hours. olestryamine given orally reduces the half-life of digitoxin from 6 days 4.5 days or prevents absorption of digitalis glycosides. Phenytoin can so be given to speed the metabolism of digitalis glycosides. ropine, 0.01 mg/kg intravenously, can increase the heart rate in the esence of digitalis heart block (Dreisbach, Handbook of Poisoning, th Ed.). Antidote should be administered by qualified medical personnel.

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## REACTIVITY

ACTIVITY:
able under normal temperatures and pressures.

IPATIBILITIES:
OXIN:
)XIDIZERS (STRONG): Fire and explosion hazard.

:OMPOSITION:
:rmal decomposition may release toxic and/or hazardous gases.

.YMERIZATION:
:ardous polymerization has not been reported to occur under normal ıperatures and pressures.

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## STORAGE AND DISPOSAL

:erve all federal, state and local regulations when storing or disposing this substance.

**Storage**

eshold Planning Quantity (TPQ):
Superfund Amendments and Reauthorization Act (SARA) Section 302 requires t each facility where any extremely hazardous substance is present in a ntity equal to or greater than the TPQ established for that substance ify the state emergency response commission for the state in which it is ted. Section 303 of SARA requires these facilities to participate in local gency response planning (40 CFR 355.30).

re away from incompatible substances.

## CONDITIONS TO AVOID

y ourn but does not ignite readily. Prevent dispersion of dust in air. Do t allow spilled material to contaminate water sources.

## SPILL AND LEAK PROCEDURES

CUPATIONAL SPILL:
not touch spilled material. Stop leak if you can do it without risk. For all spills, take up with sand or other absorbent material and place into ntainers for later disposal. For small dry spills, with a clean shovel ace material into clean, dry container and cover. Move containers from ill area. For larger spills, dike far ahead of spill for later disposal. ep unnecessary people away. Isolate hazard area and deny entry.

portable Quantity (RQ): 1 pound
e Superfund Amendments and Reauthorization Act (SARA) Section 304 requires at a release equal to or greater than the reportable quantity for this bstance be immediately reported to the local emergency planning committee d the state emergency response commission (40 CFR 355.40). If the release of is substance is reportable under CERCLA Section 103, the National Response nter must be notified immediately at (800) 424-8802 or (202) 426-2675 in the tropolitan Washington, D.C. area (40 CFR 302.6).

## PROTECTIVE EQUIPMENT

TILATION:
vide local exhaust or process enclosure ventilation to meet the published osure limits. Ventilation equipment should be explosion-proof if explosive centrations of dust, vapor or fume are present.

PIRATOR:
following respirators are recommended based on information found in the hysical data, toxicity and health effects sections. They are ranked in rder from minimum to maximum respiratory protection.
specific respirator selected must be based on contamination levels found n the work place, must be based on the specific operation, must not exceed he working limits of the respirator and must be jointly approved by the ational Institute for Occupational Safety and Health and the Mine Safety nd Health Administration (NIOSH-MSHA).

ny type 'C' supplied-air respirator with a full facepiece operated in pressure-demand or other positive pressure mode or with a full facepiece, helmet or hood operated in continuous-flow mode.

ny self-contained breathing apparatus with a full facepiece operated in pressure-demand or other positive pressure mode.

FIREFIGHTING AND OTHER IMMEDIATELY DANGEROUS TO LIFE OR HEALTH CONDITIONS:

ny self-contained breathing apparatus that has a full facepiece and is operated in a pressure-demand or other positive-pressure mode.

Any supplied-air respirator that has a full facepiece and is operated in a pressure-demand or other positive-pressure mode in combination with an auxiliary self-contained breathing apparatus operated in pressure-demand or other positive-pressure mode.



CLOTHING:
Employee must wear appropriate protective (impervious) clothing and equipment to prevent any possibility of skin contact with this substance.

GLOVES:
Employee must wear appropriate protective gloves to prevent contact with this substance.

EYE PROTECTION:
Employee must wear splash-proof or dust-resistant safety goggles and a faceshield to prevent contact with this substance.

Emergency wash facilities:
Where there is any possibility that an employee's eyes and/or skin may be exposed to this substance, the employer should provide an eye wash fountain and quick drench shower within the immediate work area for emergency use.

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CREATION DATE: 06/03/87 REVISION DATE: 06/30/94

MATERIAL SAFETY DATA SHEET



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MDL INFORMATION SYSTEMS, INC.
14600 CATALINA STREET
SAN LEANDRO, CA 94577
1-800-635-0064 OR
1-510-895-1313

FOR EMERGENCY SOURCE INFORMATION
CONTACT: 1-615-366-2000 USA

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## SUBSTANCE IDENTIFICATION

CAS NUMBER: 147-24-0
RTECS NUMBER: KR7000000

SUBSTANCE: DIPHENHYDRAMINE HYDROCHLORIDE

TRADE NAMES/SYNONYMS:
2-(DIPHENYLMETHOXY)-N,N-DIMETHYLETHANAMINE HYDROCHLORIDE;
2-(DIPHENYLMETHOXY)-N,N-DIMETHYLETHYLAMINE HYDROCHLORIDE;
ETHANAMINE, 2-(DIPHENYLMETHOXY)-N,N-DIMETHYL-, HYDROCHLORIDE;
ETHYLAMINE, 2-(DIPHENYLMETHOXY)-N,N-DIMETHYL-, HYDROCHLORIDE;
2-(BENZHYDRYLOXY)-N,N-DIMETHYLETHYL AMINE HYDROCHLORIDE;
BENADRYL HYDROCHLORIDE; BENZHYDRAMINE HYDROCHLORIDE;
DIFENHYDRAMINE HYDROCHLORIDE; BENADRYL; C17H22CLNO; OHS08079

CHEMICAL FAMILY:
Amine, alkyl-aryl

Ether

MOLECULAR FORMULA: (C6H5)2-C-H-O-C-H2-C-H2-N-(CH3)2.H-CL

MOLECULAR WEIGHT: 291.82

CERCLA RATINGS (SCALE 0-3): HEALTH=3 FIRE=1 REACTIVITY=0 PERSISTENCE=1
NFPA RATINGS (SCALE 0-4): HEALTH=U FIRE=1 REACTIVITY=0

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## COMPONENTS AND CONTAMINANTS

COMPONENT: DIPHENHYDRAMINE HYDROCHLORIDE PERCENT: 100.00
CAS# 147-24-0

EXPOSURE LIMITS:
No occupational exposure limits established by OSHA, ACGIH, or NIOSH.

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## PHYSICAL DATA

DESCRIPTION: Odorless, white crystalline powder with a bitter taste; slowly darkens on exposure to light. MELTING POINT: 331-338 F (166-170 C)

SPECIFIC GRAVITY: not available PH: 5.5 @ 1% SOLUBILITY IN WATER: 100%

SOLVENT SOLUBILITY: Soluble in alcohol, chloroform; moderately soluble in acetone; very slightly soluble in benzene and ether.

## FIRE AND EXPLOSION DATA

FIRE AND EXPLOSION HAZARD:
Slight fire hazard when exposed to heat or flame.

Dust-air mixtures may ignite or explode.

FIREFIGHTING MEDIA:
Dry chemical, carbon dioxide, water spray or regular foam (1993 Emergency Response Guidebook, RSPA P 5800.6).

For larger fires, use water spray, fog or regular foam (1993 Emergency Response Guidebook, RSPA P 5800.6).

FIREFIGHTING:
Move container from fire area if you can do it without risk (1993 Emergency Response Guidebook, RSPA P 5800.6, Guide Page 53).

Extinguish using agent suitable for type of surrounding fire. Avoid breathing vapors and dusts. Keep upwind.

## TOXICITY

DIPHENHYDRAMINE HYDROCHLORIDE:
TOXICITY DATA: 60 mg/kg/6 hours intermittent skin-child TDLo; 500 mg/kg oral-rat LD50; 114 mg/kg oral-mouse LD50; 280 mg/kg oral-guinea pig LD50; 362 mg/kg subcutaneous-rat LD50; 99200 ug/kg subcutaneous-mouse LD50; 40 mg/kg subcutaneous-guinea pig LD50; 63 mg/kg intramuscular-pigeon LD50; 82 mg/kg intraperitoneal-rat LD50; 56 mg/kg intraperitoneal-mouse LD50; 80 mg/kg intraperitoneal-mammal LD50; 75 mg/kg intraperitoneal-guinea pig LD50; 35 mg/kg intravenous-rat LD50; 20 mg/kg intravenous-mouse LD50; 10 mg/kg intravenous-rabbit LD50; 24 mg/kg intravenous-dog LD50; 18 mg/kg intravenous-hamster LD50; mutagenic data (RTECS); reproductive effects data (RTECS); tumorigenic data (RTECS).
CARCINOGEN STATUS: None.
ACUTE TOXICITY LEVEL: Toxic by ingestion.
TARGET EFFECTS: Central nervous system depressant. Poisoning may affect the brain.
AT INCREASED RISK FROM EXPOSURE: Persons with a history of increased intraocular pressure, stenosing peptic ulcer, pyloroduodenal obstruction, symptomatic prostatic hypertrophy, bladder-neck obstruction, hypertension, hyperthyroidism, cardiovascular disease or lower respiratory disease, including asthma.
ADDITIONAL DATA: May cross the placenta. Interactions with medications have been reported. Alcohol may enhance the toxic effects.

## HEALTH EFFECTS AND FIRST AID

INHALATION:
DIPHENHYDRAMINE HYDROCHLORIDE:
ACUTE EXPOSURE- Application of antihistamines to mucous membranes may cause sensitivity reactions in previously exposed persons.
CHRONIC EXPOSURE- Prolonged or repeated exposure to antihistamines may

cause sensitization.

FIRST AID- Remove from exposure area to fresh air immediately. Perform artificial respiration if necessary. Keep person warm and at rest. Treat symptomatically and supportively. Get medical attention immediately.

SKIN CONTACT:
DIPHENHYDRAMINE HYDROCHLORIDE:
ACUTE EXPOSURE- Contact with antihistamines may cause sensitivity reactions in previously exposed persons.
CHRONIC EXPOSURE- Prolonged or repeated contact with antihistamines may cause sensitization.

FIRST AID- Remove contaminated clothing and shoes immediately. Wash with soap or mild detergent and large amounts of water until no evidence of chemical remains (at least 15-20 minutes). Get medical attention immediately.

EYE CONTACT:
DIPHENHYDRAMINE HYDROCHLORIDE:
ACUTE EXPOSURE- Exposure to antihistamines may cause allergic and irritating conjunctival reactions in previously exposed persons.
CHRONIC EXPOSURE- Prolonged or repeated exposure to antihistamines may cause sensitization.

FIRST AID- Wash eyes immediately with large amounts of water or normal saline, occasionally lifting upper and lower lids, until no evidence of chemical remains (at least 15-20 minutes). Get medical attention immediately.

INGESTION:
DIPHENHYDRAMINE HYDROCHLORIDE:
NARCOTIC/TOXIC.
ACUTE EXPOSURE- May cause thickening of bronchial secretions, epigastric distress, disturbed coordination, dizziness, sleepiness and sedation. Less common effects may include dryness of mouth, nose and throat, tightness of chest, wheezing, nasal stuffiness, urticaria, drug rash, photosensitivity, excessive perspiration, blurred vision, diplopia, tinnitus, acute labyrinthitis, nausea, vomiting, diarrhea, constipation, anorexia, urinary frequency, difficulty in urination, urinary retention, palpitations, tachycardia, extrasystoles, hypotension, hemolytic anemia, thrombocytopenia, agranulocytosis, excitation, nervousness, tremor, euphoria, neuritis, convulsions, tingling, weakness and heaviness of the hands, headache, fatigue, chills, diminished mental alertness, confusion, restlessness, irritability, insomnia and early menses. Anaphylactic shock is possible. A massive dose may cause impaired consciousness, fixed and dilated pupils, flushing, hallucinations, coma and death by cardiopulmonary arrest.
CHRONIC EXPOSURE- An increase in incidences of cleft palates has been reported in children whose mothers had taken diphenhydramine hydrochloride frequently during the first trimester of pregnancey. Animal test results report fetal malformations such as cleft palate, cryptorchid testes, hydronephrosis and deficient cranial ossification in cases of maternal exposure in early pregnancy. Exposed animals have developed moderate to severe chronic inflammatory foci in the lungs, congestion of the spleen, slight edema of the liver, mild congestion and scattered petechial hemorrhages of the intestinal mucosa. In the thyroid gland, mild depletion of colloid substance and mild follicular cell hypertrophy have been reported. Rats exposed to diphenhydramine hydrochloride did not exhibit

any significant increase in tumor incidences. Simultaneous exposure to both diphenhydramine hydrochloride and sodium nitrite produced a significant increase in incidences of liver neoplasms in comparison with nitrite-dosed control animals.

FIRST AID- If vomiting does not completely empty the stomach, proceed with the following: Induce emesis with syrup of ipecac and water. When vomiting occurs, keep head lower than hips to help prevent aspiration. Do not give anything by mouth or induce vomiting if person is unconscious or otherwise unable to swallow. Treat symptomatically and supportively. Get medical attention immediately. Qualified medical personnel should consider performing gastric lavage (Dreisbach & Robertson; Handbook of Poisoning; 12th Ed.).

ANTIDOTE:
The following antidote has been recommended. However, the decision as to whether the severity of poisoning requires administration of any antidote and actual dose required should be made by qualified medical personnel.

POISONING FROM ANTIHISTAMINES:
Give physostigmine salicylate intravenously, 0.5-2 mg diluted in saline over a 5 minute time period with electrocardiographic control. Physostigmine is contraindicated in the presence of asthma, cardiac or vascular disease, or intestinal or urinary obstruction. Atropine, 1 mg, should be available for immediate injection to reverse physostigmine toxicity. (Dreisbach, Handbook of Poisoning, 11th Ed.). Antidote should be administered by qualified medical personnel.

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## REACTIVITY

REACTIVITY:
Stable under normal temperatures and pressures.

INCOMPATIBILITIES:
DIPHENHYDRAMINE HYDROCHLORIDE:
OXIDIZERS (STRONG): Fire and explosion hazard.

DECOMPOSITION:
Thermal decomposition products may include toxic oxides of nitrogen and carbon and toxic and corrosive fumes of chlorides.

POLYMERIZATION:
Hazardous polymerization has not been reported to occur under normal temperatures and pressures.

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## STORAGE AND DISPOSAL

Observe all federal, state and local regulations when storing or disposing of this substance.

**Storage**

Store away from incompatible substances.

Keep container tightly closed. Protect from exposure to air or light.

## CONDITIONS TO AVOID

May burn but does not ignite readily. Prevent dispersion of dust in air. Do not allow spilled material to contaminate water sources.

## SPILL AND LEAK PROCEDURES

OCCUPATIONAL SPILL:
Do not touch spilled material. Stop leak if you can do it without risk. For small spills, take up with sand or other absorbent material and place into containers for later disposal. For small dry spills, with a clean shovel place material into clean, dry container and cover. Move containers from spill area. For larger spills, dike far ahead of spill for later disposal. Keep unnecessary people away. Isolate hazard area and deny entry.

## PROTECTIVE EQUIPMENT

VENTILATION:
Provide local exhaust or process enclosure ventilation system.

RESPIRATOR:
The following respirators are recommended based on information found in the physical data, toxicity and health effects sections. They are ranked in order from minimum to maximum respiratory protection.
The specific respirator selected must be based on contamination levels found in the work place, must be based on the specific operation, must not exceed the working limits of the respirator and must be jointly approved by the National Institute for Occupational Safety and Health and the Mine Safety and Health Administration (NIOSH-MSHA).

Any type 'C' supplied-air respirator with a full facepiece operated in pressure-demand or other positive pressure mode or with a full facepiece, helmet or hood operated in continuous-flow mode.

Any self-contained breathing apparatus with a full facepiece operated in pressure-demand or other positive pressure mode.

FOR FIREFIGHTING AND OTHER IMMEDIATELY DANGEROUS TO LIFE OR HEALTH CONDITIONS:

Any self-contained breathing apparatus that has a full facepiece and is operated in a pressure-demand or other positive-pressure mode.

Any supplied-air respirator that has a full facepiece and is operated in a pressure-demand or other positive-pressure mode in combination with an auxiliary self-contained breathing apparatus operated in pressure-demand or other positive-pressure mode.

CLOTHING:
Employee must wear appropriate protective (impervious) clothing and equipment to prevent any possibility of skin contact with this substance.

GLOVES:
Employee must wear appropriate protective gloves to prevent contact with this

substance.

EYE PROTECTION:
Employee must wear splash-proof or dust-resistant safety goggles and a faceshield to prevent contact with this substance.

Emergency wash facilities:
Where there is any possibility that an employee's eyes and/or skin may be exposed to this substance, the employer should provide an eye wash fountain and quick drench shower within the immediate work area for emergency use.

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CREATION DATE: 04/12/90 REVISION DATE: 07/08/94

ORIGINAL

# MATERIAL SAFETY DATA SHEET

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PATIONAL HEALTH SERVICES, INC.
WEST 42ND STREET, 12TH FLOOR
W YORK, NEW YORK 10036
800-445-MSDS (1-800-445-6737) OR
212-789-3535

FOR EMERGENCY SOURCE INFORMATION
CONTACT: 1-615-366-2000 USA

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## SUBSTANCE IDENTIFICATION

CAS NUMBER: 9041-08-1
RTECS NUMBER: MI0850000

BSTANCE: HEPARIN SODIUM

ADE NAMES/SYNONYMS:
SODIUM HEPARINATE; SODIUM HEPARIN; SODIUM ACID HEPARIN; PULARIN; LIQUAEMIN; LIQUEMIN; LIQUAEMIN SODIUM; HEPATHROM; DEPO-HEPARIN; HEPARIN, SODIUM SALT; HEPARIN LOCK FLUSH; HEPRINAR; HEPARIN; LIPO-HEPIN; PANHEPRIN; C240H320N20S40NA60; OHS10655

EMICAL FAMILY:
lysaccharide

lt

ECULAR FORMULA: (C12-H16-N-S2-NA3)20

ULAR WEIGHT: 1200 (approx)

CLA RATINGS (SCALE 0-3): HEALTH=3 FIRE=1 REACTIVITY=0 PERSISTENCE=3
A RATINGS (SCALE 0-4): HEALTH=U FIRE=1 REACTIVITY=0

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## COMPONENTS AND CONTAMINANTS

PONENT: HEPARIN SODIUM PERCENT: 100.0
CAS# 9041-08-1

ER CONTAMINANTS: NONE.

OSURE LIMITS:
o occupational exposure limits established by OSHA, ACGIH, or NIOSH.

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## PHYSICAL DATA

CRIPTION: Odorless, white or off-white to pale grayish-brown amorphous

der. MELTING POINT: not available SPECIFIC GRAVITY: not available

5.0-7.5 @ 1% soln SOLUBILITY IN WATER: 5%

VENT SOLUBILITY: Soluble in saline solution and glacial acetic acid; st insoluble in alcohol, acetone, benzene, chloroform and ether.

## FIRE AND EXPLOSION DATA

k.. AND EXPLOSION HAZARD:
ight fire hazard when exposed to heat or flame.

st-air mixtures may ignite or explode.

REFIGHTING MEDIA:
y chemical, carbon dioxide, water spray or regular foam
993 Emergency Response Guidebook, RSPA P 5800.6).

r larger fires, use water spray, fog or regular foam
993 Emergency Response Guidebook, RSPA P 5800.6).

REFIGHTING:
ve container from fire area if you can do it without risk. Do not scatter
illed material with high-pressure water streams. Dike fire-control water for
:er disposal (1993 Emergency Response Guidebook, RSPA P 5800.6, Guide
ge 31).

: agents suitable for type of surrounding fire. Avoid breathing hazardous
)ors, keep upwind.

## TOXICITY

'ARIN SODIUM:
:ICITY DATA: 7 mg/kg/4 days subcutaneous-man TDLo; 3400 units/kg/17 days
ntermittent subcutaneous-woman TDLo; 1400 units/kg/1 week intermittent
ubcutaneous-woman TDLo; 1150 units/kg subcutaneous-mouse LD50; 700
nits/kg/13 days intermittent intravenous-woman TDLo; 354 mg/kg
ntravenous-rat LD50; 2800 mg/kg intravenous-mouse LD50; 1 gm/kg
ntravenous-dog LD50; 2800 mg/kg unreported-mouse LD50; reproductive effects
ata (RTECS).
CINOGEN STATUS: None.
TE TOXICITY LEVEL: Insufficient data.
GET EFFECTS: Poisoning may affect clotting of the blood.
INCREASED RISK FROM EXPOSURE: Persons with blood dyscrasias, bleeding
endencies, liver and kidney dysfunction, ulcers of the gastrointestinal
ract, hypertension, bacterial endocarditis, and pre-menopausal women.
ITIONAL DATA: Heparin sodium is an anticoagulant drug. Therapeutic
arenteral administration may cause hemorrhages at any site,
ypersensitivity reactions, thrombocytopenia possibly leading to
evere thromboembolic complications including skin necrosis, gangrene
equiring amputation, myocardial infarction, pulmonary embolism, stroke
nd death. Renal dysfunction, osteoporosis and subsequent spontaneous
ractures may occur following prolonged high doses. Other reported effects
nclude suppression of aldosterone synthesis, delayed transient alopecia,
riapism, and rebound hyperlipemia. Heparin does not cross the placenta
nd has not been associated with fetal malformations. However, fetal
tality or prematurity has occurred in about one third of pregnancies
nére heparin was administered. Interactions with medications have been
:ported.

HEALTH EFFECTS AND FIRST AID

LATION:
EPARIN SODIUM:
ACUTE EXPOSURE- No data available.
CHRONIC EXPOSURE- No data available.

IRST AID- Remove from exposure area to fresh air immediately. Perform artificial respiration if necessary. Keep person warm and at rest. Treat symptomatically and supportively. Get medical attention immediately.

IN CONTACT:
PARIN SODIUM:
ACUTE EXPOSURE- Absorption may occur through damaged skin.
CHRONIC EXPOSURE- No data available.

RST AID- Remove contaminated clothing and shoes immediately. Wash with soap or mild detergent and large amounts of water until no evidence of chemical remains (at least 15-20 minutes). Get medical attention immediately.

E CONTACT:
PARIN SODIUM:
ACUTE EXPOSURE- No data available.
CHRONIC EXPOSURE- Repeated application of a 5% solution in water to rabbit eyes produced no injury. However, a 30% solution injured the corneal epithelium only slightly.

RST AID- Wash eyes immediately with large amounts of water or normal saline, occasionally lifting upper and lower lids, until no evidence of chemical remains (at least 15-20 minutes). Get medical attention immediately.

ESTION:
PARIN SODIUM:
ACUTE EXPOSURE- Heparin sodium is reported to be inactive and unabsorbed following oral administration.
CHRONIC EXPOSURE- No data available.

ST AID- If vomiting occurs, keep head lower than hips to help prevent aspiration. Treat symptomatically and supportively. Get medical attention if needed.

IDOTE:
the event of massive hemorrhage, protamine sulfate should be given slow intravenous infusion over a 1-3 minute period. No more than 50 mg uld be administered in any 10 minute period. If antidote is given within ew minutes of heparin overdosage, 1-1.5 mg of protamine sulfate can used for each 100 units of heparin administered. If 30 minutes to 1 hour elapsed since the heparin overdosage, 0.5-0.75 mg of protamine sulfate uld be used per 100 units of heparin. If more than 2 hours have elapsed, 5-0.375 mg of protamine sulfate should be administered per 100 units of arin. (Ellenhorn and Barceloux, Medical Toxicology, Diagnosis and Treatment uman Poisoning, 1st Ed). Antidote should be administered by qualified cal personnel.

## REACTIVITY

ACTIVITY:
able under normal temperatures and pressures.

COMPATIBILITIES:
PARIN SODIUM:
OXIDIZERS (STRONG): Fire and explosion hazard.

COMPOSITION:
ermal decomposition may release toxic oxides of carbon, nitrogen, sulfur
d sodium.

LYMERIZATION:
zardous polymerization has not been reported to occur under normal
mperatures and pressures.

## STORAGE AND DISPOSAL

serve all federal, state and local regulations when storing or disposing
this substance.

**Storage**

in a cool, dry place; keep container tightly closed when not in use.

tect from freezing.

re away from incompatible substances.

## CONDITIONS TO AVOID

burn but does not ignite readily. Avoid contact with strong oxidizers,
essive heat, sparks, or open flame.

## SPILL AND LEAK PROCEDURES

UPATIONAL SPILL:
ep up and place in suitable clean, dry containers for reclamation or later
posal. Do not flush spilled material into sewer. Keep unnecessary people
y.

## PROTECTIVE EQUIPMENT

TILATION:
ride local exhaust ventilation. Ventilation equipment should be
losion-proof if explosive concentrations of dust, vapor or fume are
nt.

IRATOR:
following respirators are recommended based on information found in the
ysical data, toxicity and health effects sections. They are ranked in

order from minimum to maximum respiratory protection.
ıe specific respirator selected must be based on contamination levels found
the work place, must be based on the specific operation, must not exceed
tne working limits of the respirator and must be jointly approved by the
National Institute for Occupational Safety and Health and the Mine Safety
and Health Administration (NIOSH-MSHA).

Any dust and mist respirator.

Any air-purifying respirator with a high-efficiency particulate filter.

Any powered air-purifying respirator with a dust and mist filter.

Any powered air-purifying respirator with a high-efficiency particulate filter.

Any type 'C' supplied-air respirator operated in the pressure-demand or other positive pressure or continuous-flow mode.

Any self-contained breathing apparatus.

R FIREFIGHTING AND OTHER IMMEDIATELY DANGEROUS TO LIFE OR HEALTH CONDITIONS:

Any self-contained breathing apparatus that has a full facepiece and is operated in a pressure-demand or other positive-pressure mode.

ny supplied-air respirator that has a full facepiece and is operated in a pressure-demand or other positive-pressure mode in combination with an auxiliary self-contained breathing apparatus operated in pressure-demand or other positive-pressure mode.

)THING:
ployee must wear appropriate protective (impervious) clothing and equipment
prevent repeated or prolonged skin contact with this substance.

)VES:
ployee must wear appropriate protective gloves to prevent contact with this
)stance.

: PROTECTION:
)loyee must wear splash-proof or dust-resistant safety goggles to prevent
: contact with this substance.

:rgency eye wash: Where there is any possibility that an employee's eyes may
exposed to this substance, the employer should provide an eye wash
ıntain within the immediate work area for emergency use.

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CREATION DATE: 01/14/85 REVISION DATE: 06/30/94

MATERIAL SAFETY DATA SHEET

# KNOLL PHARMACEUTICAL COMPANY

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201/887

ORIGI...

HEALTH
FLAMMABILITY
REACTIVITY
PERSONAL PROTECTION
NC-L503R © 1985 NPCA

## SECTION I

**CHEMICAL NAME** Hydromorphone Hydrochloride **TRADE NAME** Dilaudid

**SYNONYMS** Dihydromorphinone Hydrochloride

**CHEMICAL FAMILY** Narcotic Analgesic (Hydrogenated Ketone Of Morphine)

**CAS REGISTRY NO.** [71-68-1]

**FORMULA** $C_{17}H_{19}NO_3 \cdot HCl$

**MOLECULAR WEIGHT** 321.80

## SECTION II - INGREDIENTS

| NAME | % | TLV | TOXICOLOGICAL DATA |
|---|---|---|---|
| Hydromorphone Hydrochloride | 100 | * | Male rat, oral $LD_{50}$ 199mg/kg<br>Upper Limit 241 Lower Limit 164<br>Female rat, oral $LD_{50}$ 172mg/kg<br>Upper Limit 216 Lower Limit 136<br>Rat subcutaneous $LD_{50}$ 51mg/kg<br>Mouse subcutaneous LDLo 95mg/kg<br>Mouse intravenous $LD_{50}$ 61mg/kg |

* not established

## SECTION III - PHYSICAL DATA

**MELTING POINT** 305-315°C (with decomposition)

**SOLUBILITY IN WATER** Approx. 30 percent

**APPEARANCE AND ODOR** Off-White Powder

## SECTION IV - FIRE AND EXPLOSION HAZARD DATA

| FLASH POINT (METHOD USED) | FLAMMABLE LIMITS | LOWER | UPPER |
|---|---|---|---|
| Unknown | Unknown | --- | --- |

**EXTINGUISHING MEDIA** ☑ WATER FOG ☑ FOAM ☑ $CO_2$ ☑ DRY CHEMICAL ☐ OTHER

| | |
|---|---|
| **SPECIAL FIREFIGHTING PROCEDURES** | Wear self contained breathing apparatus and protective clothing to prevent contact with skin and eyes. |
| **UNUSUAL FIRE AND EXPLOSION HAZARDS** | Emits toxic fumes under fire conditions. |

## SECTION V - HEALTH HAZARD DATA

ORIGINAL

**THRESHOLD LIMIT VALUE** Not established

**EFFECTS OF OVEREXPOSURE** Overexposure to Dilaudid is characterized by respiratory depression, somnolence progressing to stupor or coma, skeletal muscle flaccidity, cold and clammy skin, constricted pupils, and sometimes bradycardia and hypotension. In serious overdosage, particularly following intravenous injection, apnea, circulatory collapse, cardiac arrest and death may occur.

**EMERGENCY AND FIRST AID PROCEDURES** Skin: wash with soap/water-get medical assistance.
Eyes: flush thoroughly with water-get medical assistance.
Inhalation: remove to fresh air-get medical assistance.
Injestion: get medical assistance.
In the treatment of overdosage, primary attention should be given to the reestablishment of adequate respiratory exchange through provision of a patent airway and institution of assisted or controlled ventilation.

## SECTION VI - REACTIVITY DATA

| | | | |
|---|---|---|---|
| TABILITY | UNSTABLE | | **CONDITIONS TO AVOID** Avoid prolonged exposure to temperatures exceeding 86°F (30°C). Avoid exposure to intense light. |
| | STABLE | ✓ | |

**NCOMPATABILITY(MATERIALS TO AVOID)** Basic conditions or compounds, oxidizing agents, metal objects or containers.

**AZARDOUS DECOMPOSITION PRODUCTS** When heated to decomposition, it emits very toxic fumes of $NO_x$ and HCl.

## SECTION VII - SPILL OR LEAK PROCEDURES

**PILL AND LEAK PROCEDURES** Take up material with a plastic scoop and place in a suitable container for disposal. Wash off small residues by flushing with plenty of water.

**ASTE DISPOSAL METHOD** Perform in compliance with all current local state and federal regulations.

## SECTION VIII - SPECIAL PROTECTION INFORMATION

**ESPIRATORY PROTECTION, VENTILATION, ROTECTIVE CLOTHING, EYE PROTECTION** Use a respirator approved for toxic dusts. Provide adequate general mechanical and local exhaust ventilation-protect eyes & skin with safety glasses gloves and protective clothing.

## SECTION IX - SPECIAL PRECAUTIONS

o not get in eyes, on skin, or on clothing.
tore in well closed light resistant container.
ash thoroughly after handling.

## SECTION X - OTHER INFORMATION

ilaudid is a Schedule @ Narcotic Regulated by the Drug Enforcement Administration (DEA)
arning: May be habit forming. Caution: Federal law prohibits dispensing without prescription
IOSH #QD2625000

PREPARED BY: W Wolff

DATE ISSUED: 03.13.85

DATE REVISED: N/A


References

1) "Dangerous Properties Of Industrial Materials", Sixth Edition, Van Nostrand Reinhold Co., New York, N.Y., 1984, p.1058

ORIGINAL

Hydromorphone Hydrochloride
Common Name
Cat # 32300
Units package size: 50 mg

# MATERIAL SAFETY DATA SHEET
## UNITED STATES PHARMACOPEIAL CONVENTION, INC.

address:
12601 Twinbrook Parkway
Rockville, MD 20852 USA

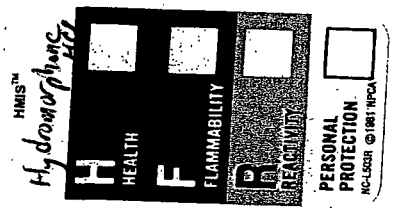
emergency and information
telephone calls:
(301) 881-0666

William M. Heller
Responsible Party

11-14-85
date prepared

WARNING STATEMENT
WARNING! REFERENCE STANDARD; NOT FOR HUMAN CONSUMPTION; AVOID INGESTION, INHALATION, SKIN CONTACT. FOR CHEMICAL TEST AND ASSAY USE ONLY.

## SECTION 1 - IDENTITY




| | |
|---|---|
| COMMON NAME | Hydromorphone Hydrochloride |
| SYNONYMS | n/a |
| CAS NUMBER | 71-68-1 |
| RTECS NUMBER | QD2625000 |
| CHEMICAL NAME | 4,5 alpha-Epoxy-3-hydroxy-17-methylmorphinan-6-one hydrochloride |
| CHEMICAL FAMILY | Narcotic analgesic (hydrogenated ketone of morphine) |
| FORMULA | C17H19NO3.HCl |

## SECTION 2 - HAZARDOUS INGREDIENTS

| | NAME | PERCENT | THRESHOLD LIMIT VALUE (UNITS) |
|---|---|---|---|
| PRINCIPAL HAZARDOUS COMPONENT(S)/[Chemical & Common name(s)] | Hydromorphone hydrochloride | Pure Material | Not Established |

## SECTION 3 - PHYSICAL AND CHEMICAL CHARACTERISTICS (Fire & Explosion Data)

| | |
|---|---|
| BOILING POINT | n/a |
| SPECIFIC GRAVITY (H2O = 1) | n/a |
| VAPOR PRESSURE (mm Hg) | n/a |

n/a = not applicable

Hydromorphone Hydrochloride
Common Name

ORIGINAL

Cat # 32300

MATERIAL SAFETY DATA SHEET
UNITED STATES PHARMACOPEIAL CONVENTION, INC.

| | |
|---|---|
| PERCENT VOLATILE BY VOLUME (%) | n/a |
| VAPOR DENSITY (AIR = 1) | n/a |
| EVAPORATION RATE | n/a |
| SOLUBILITY IN WATER | Approx. 30% |
| REACTIVITY IN WATER | n/a |
| APPEARANCE AND ODOR | Off-white powder |
| FLASH POINT | n/a |
| FLAMMABLE LIMITS IN AIR % BY VOLUME | LOWER n/a UPPER n/a |
| EXTINGUISHER MEDIA | Water spray, dry chemical, carbon dioxide or foam as appropriate for surrounding fire and materials. |
| AUTO-IGNITION TEMPERATURE | n/a |
| SPECIAL FIRE FIGHTING PROCEDURES | As with all fires, evacuate personnel to safe area. Firefighters should use self-contained breathing equipment and protective clothing. |
| UNUSUAL FIRE AND EXPLOSION HAZARDS | This material is assumed to be combustible. As with all dry powders it is advisable to ground mechanical equipment in contact with dry material to dissipate the potential buildup of static electricity. When heated to decomposition material emits toxic fumes. Emits toxic fumes under fire conditions. |

## SECTION 4 - PHYSICAL HAZARDS

| | |
|---|---|
| STABILITY | ( ) Unstable ( X ) Stable |
| CONDITIONS TO AVOID | Material is stable from a safety point of view. Avoid intense light. |
| INCOMPATABILITY (MATERIALS TO AVOID) | Basic conditions or compounds, oxidizing agents, metal objects or contaienrs. |
| HAZARDOUS DECOMPOSITION PRODUCTS | When heated to decomposition material emits toxic fumes. Emits toxic fumes under fire conditions. |
| HAZARDOUS POLYMERIZATION | ( ) May Occur ( X ) Will Not Occur |

---

= not applicable

Hydromorphone Hydrochloride
Common Name

ORIGINAL

Cat # 32300

MATERIAL SAFETY DATA SHEET
UNITED STATES PHARMACOPEIAL CONVENTION, INC.

## SECTION 5 - HEALTH HAZARDS

| | |
|---|---|
| THRESHOLD LIMIT VALUE | None established |
| SIGNS AND SYMPTOMS OF OVEREXPOSURE | Possible allergic reaction to dust if inhaled, ingested or in contact with skin. Respiratory depression, somnolence progressing to stupor or coma, skeletal muscle flaccidity, cold and clammy skin, constricted pupils, and sometimes bradycardia and hypotension. In serious overdosage, particularly following intravenous injection, apnea, circulatory collapse, cardiac arrest and death may occur. |
| ACUTE | Eye, skin and/or respiratory tract irritation |
| CHRONIC | Possible hypersensitization |
| PRECAUTIONS TO CONSIDER | Persons developing hypersensitivity (anaphylactic) reactions must receive immediate medical attention. Material may be irritating to mucous membranes and respiratory tract. As a general rule, when handling USP Reference Standards avoid all contact and inhalation of dust, fumes, mists, and/or vapors associated with the material. Keep container tightly closed and use with adequate ventilation; wash thoroughly after handling. Individuals working with chemicals should consider all chemicals to be potentially hazardous even if their individual hazards may be uncharacterized or unknown. |
| EDICAL CONDITIONS AGGRAVATED BY EXPOSURE | Hypersensitivity to material |

| | | | |
|---|---|---|---|
| HEMICAL LISTED AS CARCINOGEN OR POTENTIAL CARCINOGEN | NATIONAL TOXICOLOGY PROGRAM | ( ) Yes | ( X ) No |
| | I. A. R. C. Monographs | ( ) Yes | ( X ) No |
| | OSHA | ( ) Yes | ( X ) No |
| | OTHER | | n/a |

| | |
|---|---|
| ACGIH TLV: n/a | OTHER EXPOSURE LIMIT(S) USED: n/a |

| | |
|---|---|
| SHA PERMISSIBLE EXPOSURE LIMIT: | Not established |
| THER EXPOSURE LIMIT USED | Not established |

'a = not applicable

Hydromorphone Hydrochloride
Common Name

ORIGINAL

Cat # 32300

MATERIAL SAFETY DATA SHEET
UNITED STATES PHARMACOPEIAL CONVENTION, INC.

| | |
|---|---|
| EMERGENCY AND FIRST AID PROCEDURES | Remove from exposure. Remove contaminated clothing. Person developing serious hypersensitivity reactions must receive immediate medical attention. Upon eye or skin contact, flush affected area with copious quantities of water. Obtain medical attention. If not breathing give artificial respiration. If breathing is difficult give oxygen. |
| 1. INHALATION | May cause irritation of respiratory tract. Remove to fresh air. |
| 2. EYES | May cause irritation. Flush with copious quantities of water. |
| 3. SKIN | May cause irritation. Flush with copious quantities of water. |
| 4. INGESTION | May cause irritation. Flush out mouth with water. |

## SECTION 6 - SPECIAL PROTECTION INFORMATION

| | |
|---|---|
| RESPIRATORY PROTECTION (SPECIFY TYPE) | NIOSH approved respirator |
| VENTILATION | Adequate |
| LOCAL EXHAUST | Recommended |
| MECHANICAL (GENERAL) | Recommended |
| OTHER | n/a |
| PROTECTIVE GLOVES | Rubber |
| EYE PROTECTION | Safety goggles |
| OTHER PROTECTIVE CLOTHING OR EQUIPMENT | Appropriate laboratory apparel, protect exposed skin |

n/a = not applicable

Hydromorphone Hydrochloride ORIGINAL
Common Name
Cat # 32300

MATERIAL SAFETY DATA SHEET
UNITED STATES PHARMACOPEIAL CONVENTION, INC.

## SECTION 7 - SPECIAL PRECAUTIONS AND SPILL/LEAK PROCEDURES

**PRECAUTIONS TO BE TAKEN IN HANDLING AND STORAGE** Store in tight container as defined in the United States Pharmacopeia. This material should be handled and stored per label and other instructions to ensure product integrity.

**OTHER PRECAUTIONS** Avoid contact with eyes, skin or clothing. Avoid breathing dust or mist. Use with adequate dust control. Wash thoroughly after handling. Wear fresh clothing daily. Wash contaminated clothing before reuse. Do not permit eating, drinking or smoking near material.

**STEPS TO BE TAKEN IN CASE MATERIAL IS SPILLED OR RELEASED** Wear approved respirator and chemically compatible gloves. Vacuum or sweep up spillage. Avoid dust. Place spillage in appropriate container for waste disposal. Wash contaminated clothing before reuse. Ventilate area and wash spill site.

**WASTE DISPOSAL METHODS** Dispose of waste in accordance with all applicable Federal, State and local laws.



ATTENTION:
This Product is Sold as a Reference Standard for Use In Chemical Analysis Not For Human Consumption.

---

○ = not applicable

ORIGINAL

# MATERIAL SAFETY DATA SHEET

## 1. CHEMICAL PRODUCT AND COMPANY IDENTIFICATION

**WYETH**
**P.O. BOX 8299**
**Philadelphia, PA 19101**
**610-688-4400**

**24 HR. Emergency Medical Information:**
**610-688-4400**
**CHEMTREC(R) USA, CAN, PR: 800-424-9300**
**International: 202-483-7616**

**SUBSTANCE: MEPERIDINE HYDROCHLORIDE, PROMETHAZINE HYDROCHLORIDE INJECTION**

~~**TRADE NAMES/SYNONYMS:**~~
MEPERGAN INJECTION; WALPB029

**PRODUCT USE:** pharmaceutical

**CREATION DATE:** Jan 08 1992
**REVISION DATE:** Jun 17 2004

## 2. COMPOSITION, INFORMATION ON INGREDIENTS

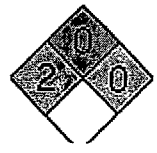
**COMPONENT:** MEPERIDINE HYDROCHLORIDE
**CAS NUMBER:** 50-13-5
**EC NUMBER (EINECS):** 200-013-3
**PERCENTAGE:** 2

**COMPONENT:** PROMETHAZINE HYDROCHLORIDE
**CAS NUMBER:** 58-33-3
**EC NUMBER (EINECS):** 200-375-2
**PERCENTAGE:** 2

**COMPONENT:** WATER
**CAS NUMBER:** 7732-18-5
**EC NUMBER (EINECS):** 231-791-2
**PERCENTAGE:** >1

## 3. HAZARDS IDENTIFICATION

**NFPA RATINGS (SCALE 0-4):** HEALTH=2 FIRE=0 REACTIVITY=0




**EMERGENCY OVERVIEW:**

ORIGINAL

**PHYSICAL FORM:** solution
**MAJOR HEALTH HAZARDS:** harmful if swallowed, central nervous system depression

**POTENTIAL HEALTH EFFECTS:**
**INHALATION:**
**SHORT TERM EXPOSURE:** irritation, skin disorders, changes in body temperature, changes in blood pressure, nausea, vomiting, loss of appetite, difficulty breathing, irregular heartbeat, headache, drowsiness, dizziness, fainting, disorientation, sleep disturbances, hallucinations, mood swings, tremors, loss of coordination, visual disturbances, pin-point pupils, bluish skin color, lung congestion, blood disorders, heart disorders, kidney damage, liver damage, convulsions, unconsciousness, coma
**LONG TERM EXPOSURE:** skin disorders, changes in body temperature, changes in blood pressure, nausea, vomiting, loss of appetite, difficulty breathing, irregular heartbeat, headache, drowsiness, dizziness, fainting, disorientation, sleep disturbances, hallucinations, mood swings, tremors, loss of coordination, visual disturbances, pin-point pupils, bluish skin color, lung congestion, blood disorders, heart disorders, kidney damage, liver damage, convulsions, unconsciousness, coma
**SKIN CONTACT:**
**SHORT TERM EXPOSURE:** irritation, allergic reactions, absorption may occur, sensitivity to light, headache, drowsiness, dizziness, loss of coordination
**LONG TERM EXPOSURE:** irritation, allergic reactions, sensitivity to light, headache, drowsiness, dizziness, loss of coordination
**EYE CONTACT:**
**SHORT TERM EXPOSURE:** irritation, pin-point pupils
**LONG TERM EXPOSURE:** irritation
**INGESTION:**
**SHORT TERM EXPOSURE:** skin disorders, itching, changes in body temperature, changes in blood pressure, nausea, vomiting, constipation, loss of appetite, difficulty breathing, irregular heartbeat, headache, drowsiness, dizziness, fainting, disorientation, hyperactivity, sleep disturbances, hallucinations, mood swings, tremors, loss of coordination, visual disturbances, pin-point pupils, bluish skin color, lung congestion, blood disorders, heart disorders, kidney damage, liver damage, convulsions, unconsciousness, coma
**LONG TERM EXPOSURE:** skin disorders, sensitivity to light, changes in body temperature, changes in blood pressure, ringing in the ears, nausea, vomiting, loss of appetite, difficulty breathing, asthma, irregular heartbeat, headache, drowsiness, fatigue, dizziness, fainting, disorientation, sleep disturbances, hallucinations, mood swings, tremors, loss of coordination, visual disturbances, pin-point pupils, bluish skin color, lung congestion, blood disorders, heart disorders, kidney damage, liver damage, convulsions, unconsciousness, coma

**CARCINOGEN STATUS:**
**OSHA:** No
**NTP:** No
**IARC:** No

## 4. FIRST AID MEASURES

**INHALATION:** If adverse effects occur, remove to uncontaminated area. Give artificial respiration if not breathing. If breathing is difficult, oxygen should be administered by qualified personnel. Get immediate medical attention.

**SKIN CONTACT:** Wash skin with soap and water for at least 15 minutes while removing contaminated clothing and shoes. Get medical attention, if needed. Thoroughly clean and dry contaminated clothing and shoes before reuse.

**EYE CONTACT:** Flush eyes with plenty of water for at least 15 minutes. Then get immediate medical attention.

**INGESTION:** If swallowed, drink plenty of water, do NOT induce vomiting. Get immediate medical attention. Induce vomiting only at the instructions of a physician. Do not give anything by mouth to unconscious or convulsive person.

**NOTE TO PHYSICIAN:** For inhalation, consider oxygen. Avoid gastric lavage or emesis.

## 5. FIRE FIGHTING MEASURES

**FIRE AND EXPLOSION HAZARDS:** No hazard expected.

**EXTINGUISHING MEDIA:** carbon dioxide, regular dry chemical, regular foam, water

**FIRE FIGHTING:** Move container from fire area if it can be done without risk. Avoid inhalation of material or combustion by-products. Stay upwind and keep out of low areas.

**FLASH POINT:** aqueous solution

## 6. ACCIDENTAL RELEASE MEASURES

**OCCUPATIONAL RELEASE:**
Stop leak if possible without personal risk. Small spills: Absorb with sand or other non-combustible material. Collect spilled material in appropriate container for disposal.

## 7. HANDLING AND STORAGE

**STORAGE:** Store and handle in accordance with all current regulations and standards. Keep separated from incompatible substances. See original container for storage recommendations.

## 8. EXPOSURE CONTROLS, PERSONAL PROTECTION

**EXPOSURE LIMITS:**
**MEPERIDINE HYDROCHLORIDE:**
125 ug/m3 recommended TWA 8 hour(s) (OEG)

**PROMETHAZINE HYDROCHLORIDE:**
60 ug/m3 recommended TWA 8 hour(s) (OEG)

**VENTILATION:** Under normal conditions of use, no special ventilation equipment is needed.

**EYE PROTECTION:** Eye protection not required, but recommended.

**CLOTHING:** Under normal conditions of use, wear suitable clothing to prevent contact with skin.

**GLOVES:** Wear appropriate chemical resistant gloves.

**RESPIRATOR:** No respirator is required under normal conditions of use. Under conditions of frequent use or heavy exposure, respiratory protection may be needed.
Respiratory protection is ranked in order from minimum to maximum.
Consider warning properties before use.
Any dust and mist respirator.
Any air-purifying respirator with a high-efficiency particulate filter.
**For Unknown Concentrations or Immediately Dangerous to Life or Health -**
Any supplied-air respirator with a full facepiece that is operated in a pressure-demand or other positive-pressure mode.
Any self-contained breathing apparatus.

## 9. PHYSICAL AND CHEMICAL PROPERTIES

**PHYSICAL STATE:** liquid
**APPEARANCE:** clear
**PHYSICAL FORM:** solution
**ODOR:** Not available
**BOILING POINT:** Not available
**FREEZING POINT:** Not available
**VAPOR PRESSURE:** Not available
**VAPOR DENSITY:** Not available
**SPECIFIC GRAVITY:** Not available
**WATER SOLUBILITY:** soluble
**PH:** 4.8-5.2
**VOLATILITY:** Not available
**ODOR THRESHOLD:** Not available
**EVAPORATION RATE:** Not available
**COEFFICIENT OF WATER/OIL DISTRIBUTION:** Not available

## 10. STABILITY AND REACTIVITY

**REACTIVITY:** Stable at normal temperatures and pressure.

**CONDITIONS TO AVOID:** Avoid heat, flames, sparks and other sources of ignition. Avoid contact with incompatible materials.

**INCOMPATIBILITIES:**
May be incompatible with acids, bases, and oxidizers.

**HAZARDOUS DECOMPOSITION:**
Thermal decomposition products: oxides of carbon

**POLYMERIZATION:** Will not polymerize.

## 11. TOXICOLOGICAL INFORMATION

ORIGINAL

**MEPERIDINE HYDROCHLORIDE:**
**TOXICITY DATA:**
43 mg/kg/2 day(s) intermittent intramuscular-woman TDLo; 13500 ug/kg/3 day(s) intermittent intramuscular-woman TDLo; 170 mg/kg oral-rat LD50; 65 mg/kg intraperitoneal-rat LD50; 175 mg/kg subcutaneous-rat LD50; 30 mg/kg intravenous-rat LD50; 280 mg/kg unreported-rat LD50; 178 mg/kg oral-mouse LD50; 104 mg/kg intraperitoneal-mouse LD50; 150 mg/kg subcutaneous-mouse LD50; 32 mg/kg intravenous-mouse LD50; 68 mg/kg intravenous-dog LD50; 100 mg/kg oral-cat LDLo; 100 mg/kg subcutaneous-cat LD50; 500 mg/kg oral-rabbit LD50; 200 mg/kg subcutaneous-rabbit LDLo; 20 mg/kg intravenous-rabbit LD50; 100 mg/kg subcutaneous-guinea pig LDLo; 111 mg/kg intramuscular-guinea pig LD50; 52 mg/kg intraperitoneal-chicken LD50; 42 mg/kg intravenous-chicken LD50; 515 mg/kg parenteral-frog LD50; 30 mg/kg/12 hour(s) intermittent intravenous-woman TDLo; 1.1 mg/kg intravenous-human TDLo; 2700 mg/kg/7 week(s) intermittent oral-dog TDLo; 22875 mg/kg/44 week(s) intermittent oral-dog TDLo; 1260 mg/kg/4 week(s) intermittent intramuscular-dog TDLo; 12200 mg/kg/44 week(s) intermittent oral-monkey TDLo; 225 mg/kg/5 day(s) intermittent intramuscular-monkey TDLo
**ACUTE TOXICITY LEVEL:**
Toxic: ingestion
**TARGET ORGANS:** central nervous system
**MEDICAL CONDITIONS AGGRAVATED BY EXPOSURE:** blood system disorders
**MUTAGENIC DATA:**
micronucleus test - mouse intraperitoneal 8 mg/kg; cytogenetic analysis - mouse intraperitoneal 2 mg/kg
**REPRODUCTIVE EFFECTS DATA:**
735 ug/kg intravenous-woman TDLo 39 week(s) pregnant female continuous; 1 mg/kg intramuscular-woman TDLo 39 week(s) pregnant female continuous; 146 mg/kg subcutaneous-hamster TDLo 8 day(s) pregnant female continuous; 250 mg/kg subcutaneous-hamster TDLo 8 day(s) pregnant female continuous
**ADDITIONAL DATA:** Alcohol may enhance the toxic effects. Interactions with drugs may occur. May impair performance of tasks requiring alertness. May cross the placenta. May be excreted in breast milk.

**PROMETHAZINE HYDROCHLORIDE:**
**TOXICITY DATA:**
3500 ug/kg/1 day(s) oral-human TDLo; 20 mg/kg oral-child TDLo; 170 mg/kg intraperitoneal-rat LD50; 400 mg/kg subcutaneous-rat LD50; 15 mg/kg intravenous-rat LD50; 255 mg/kg oral-mouse LD50; 160 mg/kg intraperitoneal-mouse LD50; 240 mg/kg subcutaneous-mouse LD50; 50 mg/kg intravenous-mouse LD50; 250 mg/kg subcutaneous-dog LD50; 35 mg/kg intraperitoneal-guinea pig LD50; 42500 ug/kg intravenous-guinea pig LD50; 525 mg/kg parenteral-rat LD50; 5.66 mg/kg subcutaneous-rat TDLo; 666 mg/kg/16 day(s) intermittent oral-rat TDLo; 2164 mg/kg/13 week(s) intermittent oral-rat TDLo; 900 mg/kg/16 day(s) intermittent oral-mouse TDLo; 2925 mg/kg/13 week(s) intermittent oral-mouse TDLo; 25 mg/kg/5 day(s) intermittent intraperitoneal-rabbit TDLo; 17149.5 mg/kg/103 week(s) intermittent oral-rat TDLo; 17149.5 mg/kg/103 week(s) intermittent oral-rat TDLo
**ACUTE TOXICITY LEVEL:**
Toxic: ingestion
**TARGET ORGANS:** central nervous system
**MEDICAL CONDITIONS AGGRAVATED BY EXPOSURE:** central nervous system disorders, eye disorders, gastrointestinal disorders, heart or cardiovascular disorders, liver disorders, respiratory disorders
**REPRODUCTIVE EFFECTS DATA:**
60 mg/kg oral-rat TDLo 5-16 day(s) pregnant female continuous; 240 mg/kg oral-rat TDLo 5-16 day(s) pregnant female continuous; 350 mg/kg parenteral-rat TDLo 1 day(s) pregnant female continuous; 350 mg/kg parenteral-rat TDLo 2 day(s) pregnant female continuous; 350 mg/kg parenteral-rat TDLo 3 day

(s) pregnant female continuous; 350 mg/kg parenteral-rat TDLo 4 day(s) pregnant female continuous; 350 mg/kg parenteral-rat TDLo 5 day(s) pregnant female continuous; 350 mg/kg parenteral-rat TDLo 6 day(s) pregnant female continuous; 350 mg/kg parenteral-rat TDLo 7 day(s) pregnant female continuous; 350 mg/kg parenteral-rat TDLo 8 day(s) pregnant female continuous; 350 mg/kg parenteral-rat TDLo 9 day(s) pregnant female continuous; 350 mg/kg parenteral-rat TDLo 10 day(s) pregnant female continuous; 350 mg/kg parenteral-rat TDLo 11 day(s) pregnant female continuous; 350 mg/kg parenteral-rat TDLo 12 day(s) pregnant female continuous; 350 mg/kg parenteral-rat TDLo 13 day(s) pregnant female continuous; 350 mg/kg parenteral-rat TDLo 10 day(s) pregnant female continuous; 350 mg/kg parenteral-rat TDLo 11 day(s) pregnant female continuous; 350 mg/kg parenteral-rat TDLo 12 day(s) pregnant female continuous; 350 mg/kg parenteral-rat TDLo 13 day(s) pregnant female continuous; 350 mg/kg parenteral-rat TDLo 14 day(s) pregnant female continuous; 350 mg/kg parenteral-rat TDLo 15 day(s) pregnant female continuous

**ADDITIONAL DATA:** May cross the placenta. May be excreted in breast milk. Alcohol may enhance the toxic effects. Interactions with drugs may occur. May cross react with similar compounds. May impair performance of tasks requiring alertness.

**HEALTH EFFECTS:**
**INHALATION:**
MEPERIDINE HYDROCHLORIDE: See information on narcotic analgesics.

**ACUTE EXPOSURE:**
NARCOTIC ANALGESICS: If sufficient quantities are absorbed, systemic poisoning may occur as detailed in acute ingestion.

PROMETHAZINE HYDROCHLORIDE: May cause irritation to the mucous membranes and upper respiratory tract.

**CHRONIC EXPOSURE:**
NARCOTIC ANALGESICS: If sufficient quantities are absorbed, systemic poisoning may occur as detailed in chronic ingestion.

PROMETHAZINE HYDROCHLORIDE: No data available.

**SKIN CONTACT:**
**ACUTE EXPOSURE:**
MEPERIDINE HYDROCHLORIDE: No data available.

PROMETHAZINE HYDROCHLORIDE: Contact may cause phototoxic reactions, contact dermatitis, urticaria, and shock. May be absorbed through the skin and cause systemic effects as detailed in chronic exposure. Sensitivity reactions, including photosensitivity, may occur in previously exposed individuals.

**CHRONIC EXPOSURE:**
MEPERIDINE HYDROCHLORIDE: No data available.

PROMETHAZINE HYDROCHLORIDE: Prolonged or repeated contact may cause central nervous system depression, ataxia, visual hallucinations, excitomotor manifestations, peripheral anticholinergic effects, and effects as in acute exposure.

**EYE CONTACT:**
**ACUTE EXPOSURE:**
MEPERIDINE HYDROCHLORIDE: Systemic administration may cause miosis. In mice, it resulted in

rapid appearance of opacities of the lens due to suppression of blinking with resultant drying of the cornea and dehydration of the lens. The effect was reversible.

PROMETHAZINE HYDROCHLORIDE: May cause irritation.

**CHRONIC EXPOSURE:**
MEPERIDINE HYDROCHLORIDE: Repeated exposure to the dust may cause blepharitis and conjunctivitis.

PROMETHAZINE HYDROCHLORIDE: No data available.

**INGESTION:**
MEPERIDINE HYDROCHLORIDE: See information on narcotic analgesics.

**ACUTE EXPOSURE:**
NARCOTIC ANALGESICS: Ingestion may cause dry mouth, slurred speech, headache, nausea, vomiting, dizziness, drowsiness, weakness, anorexia, insomnia, depressed cough reflex, tremors, visual disturbances and impaired mental and physical performance. Pruritus, sweating and a slight decrease in in body temperature may occur. There may be mood changes, euphoria, dysphoria and apathy. In some individuals anxiety, agitation and excitement may pass into delirium or mania. Hallucinations have been reported. Analgesia and increased pain tolerance may occur, but as the analgesia wears off, there may be an increased sensitivity to pain. With higher doses, muscular rigidity may occur, and central nervous system depression may progress with stupor, sedation, unconsciousness and coma in which the pupils become pinpoint and skeletal muscles are flaccid, although positive babinski reflexes and muscle twitching may occur. There may be convulsions, especially with hypoxemia. Respiratory depression may occur with slow, shallow, irregular breathing, apnea and cyanosis. Pulmonary edema is common. Other effects on the respiratory system may include bronchospasm and aspiration pneumonia. Peripheral vasodilation may result in flushing in the skin of the face, neck and upper thorax and in syncope from orthostatic hypotension. More serious effects on the cardiovascular system may include hypertension, arrhythmias, shock, acute ventricular failure and cardiac arrest. Rashes, pruritus, edema and rarely hemorrhagic urticaria may occur. Effects on the gastrointestinal system may include decreased gastric motility, constipation, fecal impaction, cramping, and increased muscle tone of the gastrointestinal and biliary tracts to the point of spasm. Depressed urine formation and urinary retention may occur. The liver may be enlarged, and tender, and liver function tests may be abnormal. Other lab findings may include mild leukocytosis with lymphocytosis, acidosis and hypoglycemia. Death is almost always due to respiratory failure.

PROMETHAZINE HYDROCHLORIDE: May cause hyperexcitability and abnormal movements.

**CHRONIC EXPOSURE:**
NARCOTIC ANALGESICS: Repeated or prolonged ingestion may cause effects as detailed in acute ingestion. Repeated use has been associated with various pulmonary pathologies, abnormal pulmonary function, increased body temperature, myoglobinuria and renal failure. Tolerance and physical and psychological dependence may develop with prolonged use. Symptoms of withdrawal may occur. Narcotic analgesics cross the placenta and are excreted in human breast milk and may result in neonatal withdrawal and death.

PROMETHAZINE HYDROCHLORIDE: May cause central nervous system depression with sedation, somnolence, blurred vision, confusion, disorientation, dizziness and drowsiness. May also cause extrapyrimidal symptoms of oculogyric crisis, torticollis, tongue protrusion, lassitude, tinnitus, incoordination, fatigue, euphoria, nervousness, diplopia, insomnia, tremors, convulsion seizures,

excitation, catatonic-like states, hysteria, and hallucinations. Cardiovascular symptoms include increased or decreased blood pressure, tachycardia, bradycardia, and faintness. Dermatologic symptoms include dermatitis, photosensitivity, and urticardia. Hematologic symptoms include leukopenia, thrombocytopenia, thrombocytopenic purpura, and agranulocytosis. Gastrointestinal effects include dry mouth, nausea, vomiting, and jaundice. Effects to the respiratory system include asthma, nasal stuffiness, respiratory depression (potentially fatal) and apnea (potentially fatal). Angioneurotic edema and neuroleptic malignant syndrome have also been reported. May also cause cholestatic jaundice.

## 12. ECOLOGICAL INFORMATION

Not available

## 13. DISPOSAL CONSIDERATIONS

Dispose in accordance with all applicable regulations.

## 14. TRANSPORT INFORMATION

**U.S. DEPARTMENT OF TRANSPORTATION:** No classification assigned.

**CANADIAN TRANSPORTATION OF DANGEROUS GOODS:** No classification assigned.

**LAND TRANSPORT ADR:** No classification assigned.

**LAND TRANSPORT RID:** No classification assigned.

**AIR TRANSPORT IATA:** No classification assigned.

**AIR TRANSPORT ICAO:** No classification assigned.

**MARITIME TRANSPORT IMDG:** No classification assigned.

## 15. REGULATORY INFORMATION

**U.S. REGULATIONS:**
**CERCLA SECTIONS 102a/103 HAZARDOUS SUBSTANCES (40 CFR 302.4):** Not regulated.

**SARA TITLE III SECTION 302 EXTREMELY HAZARDOUS SUBSTANCES (40 CFR 355.30):** Not regulated.

**SARA TITLE III SECTION 304 EXTREMELY HAZARDOUS SUBSTANCES (40 CFR 355.40):** Not regulated.

**SARA TITLE III SARA SECTIONS 311/312 HAZARDOUS CATEGORIES (40 CFR 370.21):**
ACUTE: Yes
CHRONIC: No
FIRE: No

ORIGINAL

REACTIVE: No
SUDDEN RELEASE: No

**SARA TITLE III SECTION 313 (40 CFR 372.65):** Not regulated.

**OSHA PROCESS SAFETY (29CFR1910.119):** Not regulated.

**STATE REGULATIONS:**
**California Proposition 65:** Not regulated.

**CANADIAN REGULATIONS:**
**WHMIS CLASSIFICATION:** Not determined.

**EUROPEAN REGULATIONS:**
**EC CLASSIFICATION (CALCULATED):** Not determined.

**NATIONAL INVENTORY STATUS:**
**U.S. INVENTORY (TSCA):** This product is exempt.

**TSCA 12(b) EXPORT NOTIFICATION:** Not listed.

## 16. OTHER INFORMATION



**The information provided in this MSDS is based upon sources believed to be accurate. However, the company assumes no responsibility for the accuracy, completeness or suitability of this information. The product user is responsible to determine the suitability of this information for their particular purposes.**

INVOICE #: 112614 CUST. #: 6135 CUSTOMER: WYETH LABORATORIES, INC.


ORIGINAL

Meperidine Hydrochloride
Common Name
Cat # 38300
Units package size: 200 mg

# MATERIAL SAFETY DATA SHEET
## UNITED STATES PHARMACOPEIAL CONVENTION, INC.

address:
12601 Twinbrook Parkway
Rockville, MD 20852 USA

emergency and information
telephone calls:
(301) 881-0666

William M. Heller
Responsible Party

10-22-85
date prepared

WARNING STATEMENT
WARNING! REFERENCE STANDARD; NOT FOR HUMAN CONSUMPTION; AVOID INGESTION, INHALATION, SKIN CONTACT. FOR CHEMICAL TEST AND ASSAY USE ONLY.

## SECTION 1 - IDENTITY

| | |
|---|---|
| COMMON NAME | Meperidine Hydrochloride |
| SYNONYMS | n/a |
| CAS NUMBER | 50-13-5 |
| RTEC NUMBER | NS5950000 |
| CHEMICAL NAME | Ethyl 1-methyl-4-phenylisonipecotate hydrochloride |
| CHEMICAL FAMILY | Analgesic (narcotic) |
| FORMULA | C15H21NO2.HCl |

## SECTION 2 - HAZARDOUS INGREDIENTS

| | NAME | PERCENT | THRESHOLD LIMIT VALUE (UNITS) |
|---|---|---|---|
| PRINCIPAL HAZARDOUS COMPONENT(S)/[Chemical & Common name(s)] | Meperidine Hydrochloride | Pure Material | Not Established |

## SECTION 3 - PHYSICAL AND CHEMICAL CHARACTERISTICS (Fire & Explosion Data)

| | |
|---|---|
| BOILING POINT | n/a |
| SPECIFIC GRAVITY (H2O = 1) | n/a |
| VAPOR PRESSURE (mm Hg) | n/a |
| PERCENT VOLATILE BY VOLUME (%) | n/a |

n/a = not applicable

ORIGINAL

MATERIAL SAFETY DATA SHEET
UNITED STATES PHARMACOPEIAL CONVENTION, INC.

| | |
|---|---|
| VAPOR DENSITY (AIR = 1) | n/a |
| EVAPORATION RATE | n/a |
| SOLUBILITY IN WATER | Very soluble |
| REACTIVITY IN WATER | n/a |
| APPEARANCE AND ODOR | Fine white crystalline powder, odorless |
| FLASH POINT | n/a |
| FLAMMABLE LIMITS IN AIR % BY VOLUME | LOWER n/a UPPER n/a |
| EXTINGUISHER MEDIA | Water spray, dry chemical, carbon dioxide or foam as appropriate for surrounding fire and materials. |
| AUTO-IGNITION TEMPERATURE | n/a |
| SPECIAL FIRE FIGHTING PROCEDURES | As with all fires, evacuate personnel to safe area. Firefighters should use self-contained breathing equipment and protective clothing. |
| UNUSUAL FIRE AND EXPLOSION HAZARDS | This material is assumed to be combustible. As with all dry powders it is advisable to ground mechanical equipment in contact with dry material to dissipate the potential buildup of static electricity. When heated to decomposition material emits toxic fumes. Emits toxic fumes under fire conditions. |

## SECTION 4 - PHYSICAL HAZARDS

| | |
|---|---|
| STABILITY | ( ) Unstable ( X ) Stable |
| CONDITIONS TO AVOID | Material is stable from a safety point of view. |
| INCOMPATABILITY (MATERIALS TO AVOID) | n/a |
| HAZARDOUS DECOMPOSITION PRODUCTS | When heated to decomposition material emits toxic fumes (nitrogen oxides). Emits toxic fumes under fire conditions. |
| HAZARDOUS POLYMERIZATION | ( ) May Occur ( X ) Will Not Occur |

n/a = not applicable

Meperidine Hydrochloride
Common Name
Cat # 38300

ORIGINAL

MATERIAL SAFETY DATA SHEET
UNITED STATES PHARMACOPEIAL CONVENTION, INC.

SECTION 5 - HEALTH HAZARDS

| | |
|---|---|
| THRESHOLD LIMIT VALUE | None established |
| SIGNS AND SYMPTOMS OF OVEREXPOSURE | [LD50: 170 mg/Kg oral-rat] The probable lethal dose for a non-addicted adult probably lies between 120 and 250 mg (oral). Possible allergic reaction to dust if inhaled, ingested or in contact with skin. Mental exhilaration, physical comfort, dizziness, drowsiness, contracted pupils (not responsive to light), reduced pulse, labored breathing |
| ACUTE | Eye, skin and/or respiratory tract irritation |
| CHRONIC | Possible hypersensitization, potential habituation, addication |
| PRECAUTIONS TO CONSIDER | Persons developing hypersensitivity (anaphylactic) reactions must receive immediate medical attention. Avoid inhalation or contact with skin. Meperidine is a narcotic and can produce drug dependence of the morphine type and therefore has the potential for abuse. In the presence of hypoventilation or apnea, oxygen should be administered and respiration should be maintained. The duration of respiratory depression following overdose may be longer than the duration of narcotic antagonist action. Material may be irritating to mucous membranes and respiratory tract. As a general rule, when handling USP Reference Standards avoid all contact and inhalation of dust, fumes, mist, and/or vapors associated with the material. Keep container tightly closed and use with adequate ventilation; wash thoroughly after handling. Individuals working with chemicals should consider all chemicals to be potentially hazardous even if their individual hazards may be uncharacterized or unknown. |
| MEDICAL CONDITIONS AGGRAVATED BY EXPOSURE | Hypersensitivity to material |

| | | | |
|---|---|---|---|
| CHEMICAL LISTED AS CARCINOGEN OR POTENTIAL CARCINOGEN | NATIONAL TOXICOLOGY PROGRAM | ( ) Yes | ( X ) No |
| | I.A.R.C. Monographs | ( ) Yes | ( X ) No |
| | OSHA | ( ) Yes | ( X ) No |
| | OTHER | | n/a |

n/a = not applicable

Meperidine Hydrochloride
Common Name
Cat # 38300

ORIGINAL

MATERIAL SAFETY DATA SHEET
UNITED STATES PHARMACOPEIAL CONVENTION, INC.

ACGIH TLV: n/a

OTHER EXPOSURE LIMIT(S) USED: n/a

OSHA PERMISSIBLE EXPOSURE LIMIT: Not established

OTHER EXPOSURE LIMIT USED Not established

EMERGENCY AND FIRST AID PROCEDURES

Remove from exposure. Remove contaminated clothing. Persons developing serious hypersensitivity reactions must receive immediate medical attention. Upon eye or skin contact, flush affected area with copious quantities of water. Obtain medical attention. Meperidine is a narcotic and can produce drug dependence of the morphine type and therefore has the potential for abuse. In the presence of hypoventilation or apnea, oxygen should be administered and respiration should be maintained. The duration of respiratory depression following overdose may be longer than the duration of narcotic antagonist action. Keep the person awake, walk person around. Keep the person warm. Emetic as recommended by physician should be given.

1. INHALATION — May cause irritation of respiratory tract. Remove to fresh air.

2. EYES — May cause irritation. Flush with copious quantities of water.

3. SKIN — May cause irritation. Flush with copious quantities of water.

4. INGESTION — May cause irritation. Flush out mouth with water.

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= not applicable

Meperidine Hydrochloride
Common Name
Cat # 38300

ORIGINAL

MATERIAL SAFETY DATA SHEET
UNITED STATES PHARMACOPEIAL CONVENTION, INC.

## SECTION 6 - SPECIAL PROTECTION INFORMATION

| | |
|---|---|
| RESPIRATORY PROTECTION (SPECIFY TYPE) | NIOSH approved respirator |
| VENTILATION | Adequate |
| LOCAL EXHAUST | Recommended |
| MECHANICAL (GENERAL) | Recommended |
| OTHER | n/a |
| PROTECTIVE GLOVES | Impervious Rubber |
| EYE PROTECTION | Safety goggles |
| OTHER PROTECTIVE CLOTHING OR EQUIPMENT | Protect exposed skin, appropriate laboratory apparel |

## SECTION 7 - SPECIAL PRECAUTIONS AND SPILL/LEAK PROCEDURES

| | |
|---|---|
| PRECAUTIONS TO BE TAKEN IN HANDLING AND STORAGE | Store in tight container as defined in the United States Pharmacopeia. This material should be handled and stored per label and other instructions to ensure product integrity. |
| OTHER PRECAUTIONS | Avoid contact with eyes, skin or clothing. Avoid breathing dust or mist. Use with adequate dust control. Wash thoroughly after handling. Wear fresh clothing daily. Wash contaminated clothing before reuse. Do not permit eating, drinking or smoking near material. |
| STEPS TO BE TAKEN IN CASE MATERIAL IS SPILLED OR RELEASED | Wear approved respirator and chemically compatible gloves. Vacuum or sweep up spillage. Avoid dust. Place spillage in appropriate container for waste disposal. Wash contaminated clothing before reuse. Ventilate area and wash spill site. |
| WASTE DISPOSAL METHODS | Dispose of waste in accordance with all applicable Federal, State and local laws. |

= not applicable

Meperidine Hydrochloride
Common Name
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ORIGINAL

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UNITED STATES PHARMACOPEIAL CONVENTION, INC.

NOTICE: The information contained herein is applicable solely to the chemical substance when used as a USP Reference Standard and does not relate to any other use of the substance described. Its use is intended by persons having technical skill and at their own discretion and risk. The information has been developed by USP staff from sources considered reliable but has not been independently verified by the USP. Therefore, the USP Convention cannot guarantee the accuracy of the information in these sources nor should the statements contained herein be considered an official expression. NO REPRESENTATION OR WARRANTY, EXPRESS OR IMPLIED, INCLUDING THE WARRANTIES OF MERCHANTABILITY AND FITNESS FOR A PARTICULAR PURPOSE is made with respect to the information contained herein.

ATTENTION:
This Product is Sold as a Reference Standard for Use In Chemical Analysis Not For Human Consumption.

---

= not applicable

ORIGINAL

# MORPHINE SULFATE

Material Safety Data Sheet

Emergency Telephone Number
314-982-5000

Mallinckrodt, Inc.
P.O. Box 5439
St. Louis, MO 63147

Effective Date: 09-23-85

## PRODUCT IDENTIFICATION:

Synonyms: 7,8-didehydro-4,5-epoxy-17-methylmorphinan-3,6-diol sulfate pentahydrate

Formula CAS No.: 6211-15-0
TSCA CAS No.: 64-31-3

Molecular Weight: 758.83

Hazardous Ingredients:

Chemical Formula: $(C_{17}H_{19}NO_3)_2 \cdot H_2SO_4 \cdot 5H_2O$

Not applicable.

## PRECAUTIONARY MEASURES

DANGER! MAY BE FATAL IF SWALLOWED. HARMFUL IF INHALED OR ABSORBED THROUGH SKIN. ALLERGEN. EXPOSURE MAY PRODUCE ALLERGIC RESPONSE.

Avoid breathing dust.
Avoid contact with eyes, skin and clothing.
Keep container closed.
Use with adequate ventilation.
Wash thoroughly after handling.

## EMERGENCY/FIRST AID

If swallowed and if patient is conscious, give water to rinse mouth, then induce vomiting by tickling back of throat with the handle of a spoon or by giving a glass of warm soapy water. Repeat several times.
If inhaled, remove to fresh air. If not breathing, give artificial respiration. If breathing is difficult, give oxygen.
In case of contact, immediately flush skin or eyes with plenty of water for at least 15 minutes.
In all cases call a physician.
SEE SECTION 5.

DOT Hazard Class: Not Regulated

## Physical Data — SECTION 1

Appearance: White powder.

Odor: Odorless.

Solubility: 6.5g in 100g of water.

Boiling Point: Not applicable.

Vapor Density (Air=1): No information found.

Melting Point: ca. 250°C (482°F). Loses some water at room temperature.

Vapor Pressure (mm Hg): No information found.

Density: ca 1.3

Evaporation Rate: No information found.

ORIGINAL

## Fire and Explosion Information — SECTION 2

**Fire:** As with most organic solids, fire is possible at elevated temperatures or by contact with an ignition source.

**Explosion:** Not considered to be an explosion hazard.

**Fire Extinguishing Media:** Water spray, dry chemical, alcohol foam or carbon dioxide.

**Special Information:** In the event of a fire, wear full protective clothing and NIOSH-approved self-contained breathing apparatus with full facepiece operated in the pressure demand or other positive pressure mode.

## Reactivity Data — SECTION 3

**Stability:** Discolors on exposure to light.

**Hazardous Decomposition Products:** Toxic gases and vapors may be released if involved in a fire.

**Hazardous Polymerization:** This substance does not polymerize.

**Incompatibilities:** Alkalies, tannin, strong oxidizing agents, borax, ferric chloride, iodides, lead acetate, mercuric chloride, gold salts.

## Leak/Spill Disposal Information — SECTION 4

Ventilate area of leak or spill. Remove all sources of ignition. Clean-up personnel may require respiratory protection from dust. All clean-up operations should be witnessed by more than one individual.

Spills: Carefully sweep up material into an appropriate container and save for reclamation or disposal. The amount of material collected should be assessed and documented.

Disposal: Notify site Drug Enforcement Agency compliance officer and local DEA office for appropriate disposal procedures.

Ensure compliance with local, state and federal regulations.

ORIGINAL

Health Hazard Information SECTION 5

A. Exposure/Health Effects

| | |
|---|---|
| Inhalation: | Narcotic. Can irritate the respiratory passages and cause sneezing or coughing but will also have an anesthetic effect. Inhalation of appreciable quantities may produce lung edema, dizziness, and respiratory difficulties, see also Ingestion, below. |
| Ingestion: | Narcotic. Human lethal dose probably 120-250 mg. In addition to its analgesic action, morphine may cause gastric disturbance with nausea, vomiting and constipation. Large amounts may cause central nervous system depression, respiratory or cardiac collapse, coma and death. |
| Skin Contact: | Not expected to cause health effects, although the possibility of absorption under conditions of skin breakage or inflammation exists. |
| Eye Contact: | Mild irritant but will also have a strong narcotic effect (pupil contraction) and the eye may serve as an absorption route to the body in general. |
| Chronic Exposure: | May cause habituation or addiction. |
| Aggravation of Pre-existing Conditions: | Some individuals may become sensitized from exposure and develop skin rashes, coughs, stuffy nose, asthma, and other allergic complaints. Sensitivity may develop soon after immediate contact or after years of exposure. |

B. FIRST AID

| | |
|---|---|
| Inhalation: | Remove to fresh air. If not breathing, give artificial respiration. If breathing is difficult, give oxygen. Call a physician. |
| Ingestion: | If patient is conscious, give water to rinse mouth, then induce vomiting by tickling back of throat with the handle of a spoon or by giving a glass of warm soapy water. Repeat several times. Get medical attention immediately. |
| Skin Exposure: | In case of contact, immediately flush skin with plenty of water for at least 15 minutes while removing contaminated clothing and shoes. Wash clothing before reuse. Call a physician immediately. |
| Eye Exposure: | In case of contact, immediately flush eyes with plenty of water for at least 15 minutes. Call a physician. |

C. TOXICITY DATA (RTECS, 1982)

Morphine sulfate anhydrous: Oral rat LD50: 461 mg/kg.
Oral mouse LD50: 670 mg/kg.
Mutation data cited.
Reproductive effects data cited.

## Occupational Control Measures — SECTION 6

| | |
|---|---|
| Airborne Exposure Limits: | None established. |
| Ventilation System: | A local exhaust system which captures the contaminant at its source is recommended to prevent dispersion of the contaminant into the workroom air. |
| Personal Respirators (NIOSH Approved) | For conditions of use where exposure to the dust is apparent, a dust/mist respirator may be worn. For emergencies, a self-contained breathing apparatus may be necessary. |
| Skin Protection: | Wear protective gloves and clean body-covering clothing. |
| Eye Protection: | Use chemical safety goggles. Contact lenses should not be worn when working with this material.<br>Maintain eye wash fountain and quick-drench facilities in work area. |

Allergic responses in sensitive individuals will disappear if removed from exposure.

## Storage and Special Information — SECTION 7

Keep in a tightly closed container, stored in a cool, dry, ventilated area. Protect from physical damage and direct sunlight.

CONTROLLED SUBSTANCE: Location of storage area must comply with all Drug Enforcment Agency regulations.

Crystallex #3
Cammer #23
Clerico - #2
Cattowski #
Johnson #18

INVOICE #: 127064 CUST. #: 6135 CUSTOMER: WYETH LABORATORIES, INC.


Nafcillin Sodium
Common Name

Cat # 45000

Units package size: 200 mg

# MATERIAL SAFETY DATA SHEET
## UNITED STATES PHARMACOPEIAL CONVENTION, INC.

address:
12601 Twinbrook Parkway
Rockville, MD 20852 USA

emergency and information
telephone calls:
(301) 881-0666

William M. Heller
Responsible Party

10-10-85
date prepared

WARNING STATEMENT
WARNING! REFERENCE STANDARD; NOT FOR HUMAN CONSUMPTION; AVOID INGESTION, INHALATION, SKIN CONTACT. FOR CHEMICAL TEST AND ASSAY USE ONLY.

## SECTION 1 - IDENTITY

| | |
|---|---|
| COMMON NAME | Nafcillin Sodium® |
| SYNONYMS | n/a |
| CAS NUMBER | 7177-50-6 (monohydrate); 985-16-0 (anhydrous) |
| RTECS NUMBER | XI0175000 (anhydrous) |
| CHEMICAL NAME | 4-Thia-1-azabicyclo [3.2.0]heptane-2-carboxylic acid, 6-[[(2-ethoxy-1-naphthalenyl)carbonyl]amino]-3,3-dimethyl-7-oxo-, monosodium salt, monohydrate [2S-(2a, 5a, 6b)]- |
| CHEMICAL FAMILY | Penicillin |
| FORMULA | C21H21N2NaO5S. H2O |

## SECTION 2 - HAZARDOUS INGREDIENTS

| | NAME | PERCENT | THRESHOLD LIMIT VALUE (UNITS) |
|---|---|---|---|
| PRINCIPAL HAZARDOUS COMPONENT(S)/[Chemical & Common name(s)] | Nafcillin Sodium | Pure Material | Not Established |

## SECTION 3 - PHYSICAL AND CHEMICAL CHARACTERISTICS (Fire & Explosion Data)

| | |
|---|---|
| BOILING POINT | n/a |
| SPECIFIC GRAVITY (H2O = 1) | n/a |
| VAPOR PRESSURE (mm Hg) | n/a |

n/a = not applicable

Nafcillin Sodium
Common Name
Cat # 45000

ORIGINAL

MATERIAL SAFETY DATA SHEET
UNITED STATES PHARMACOPEIAL CONVENTION, INC.

| | |
|---|---|
| PERCENT VOLATILE BY VOLUME (%) | n/a |
| VAPOR DENSITY (AIR = 1) | n/a |
| EVAPORATION RATE | n/a |
| SOLUBILITY IN WATER | Freely soluble |
| REACTIVITY IN WATER | n/a |
| APPEARANCE AND ODOR | White to yellowish white powder having not more than a characteristic odor |
| FLASH POINT | n/a |
| FLAMMABLE LIMITS IN AIR % BY VOLUME | LOWER n/a UPPER n/a |
| EXTINGUISHER MEDIA | Water spray, dry chemical, carbon dioxide or foam as appropriate for surrounding fire and materials. |
| AUTO-IGNITION TEMPERATURE | n/a |
| SPECIAL FIRE FIGHTING PROCEDURES | As with all fires, evacuate personnel to safe area. Firefighters should use self-contained breathing equipment and protective clothing. |
| UNUSUAL FIRE AND EXPLOSION HAZARDS | This material is assumed to be combustible. As with all dry powders it is advisable to ground mechanical equipment in contact with dry material to dissipate the potential buildup of static electricity. When heated to decomposition material emits toxic fumes. Emits toxic fumes under fire condition. |

## SECTION 4 - PHYSICAL HAZARDS

| | |
|---|---|
| STABILITY | ( ) Unstable ( X ) Stable |
| CONDITIONS TO AVOID | Material is stable from a safety point of view. |
| INCOMPATABILITY (MATERIALS TO AVOID) | n/a |
| HAZARDOUS DECOMPOSITION PRODUCTS | When heated to decomposition material emits toxic fumes. Emits toxic fumes under fire conditions. |
| HAZARDOUS POLYMERIZATION | ( ) May Occur ( X ) Will Not Occur |

n/a = not applicable

ORIGINAL

Nafcillin Sodium
Common Name

Cat # 45000

MATERIAL SAFETY DATA SHEET
UNITED STATES PHARMACOPEIAL CONVENTION, INC.

## SECTION 5 - HEALTH HAZARDS

| | |
|---|---|
| THRESHOLD LIMIT VALUE | None established |
| SIGNS AND SYMPTOMS OF OVEREXPOSURE | Possible allergic reaction to dust if inhaled, ingested or in contact with skin. Reported symptoms include skin rash and labored breathing. |
| ACUTE | Eye, skin and/or respiratory tract irritation, skin rash, hives, itching, wheezing, nausea, chills, fever |
| CHRONIC | Possible hypersensitization |
| PRECAUTIONS TO CONSIDER | Persons developing hypersensitivity (anaphylactic) reactions must receive immediate medical attention. Harmful if swallowed, inhaled or absorbed through skin. Individuals with previous history of significant allergy (especially to antibiotics) and/or asthma should avoid potential exposure to this material. Individuals hypersensitive to one penicillin may be hypersensitive to other penicillins also. Individuals hypersensitive to cephalosporins, griseofulvin, or penicillamine may be hypersensitive to penicillins also. Allergic reactions are more common than frank toxicity. Anaphylactic shock is rare, but can follow a one-microgram test dose. It is managed by epinephrine. Accelerated (one to 72 hours) and late urticarial reactions are much more common. Material may be irritating to mucous membranes and respiratory tract. As a general rule, when handling USP Reference Standards avoid all contact and inhalation of dust, fumes, mist, and/or vapors associated with the material. Keep container tightly closed and use with adequate ventilation; wash thoroughly after handling. Individuals working with chemicals should consider all chemicals to be potentially hazardous even if their individual hazards may be uncharacterized or unknown. |
| MEDICAL CONDITIONS AGGRAVATED BY EXPOSURE | Hypersensitivity to material |

| | | | |
|---|---|---|---|
| CHEMICAL LISTED AS CARCINOGEN OR POTENTIAL CARCINOGEN | NATIONAL TOXICOLOGY PROGRAM | ( ) Yes | ( X ) No |
| | I.A.R.C. Monographs | ( ) Yes | ( X ) No |
| | OSHA | ( ) Yes | ( X ) No |
| | OTHER | | n/a |

n/a = not applicable

Nafcillin Sodium
Common Name
Cat # 45000

ORIGINAL

MATERIAL SAFETY DATA SHEET
UNITED STATES PHARMACOPEIAL CONVENTION, INC.

| | | | |
|---|---|---|---|
| | ACGIH TLV: | n/a | OTHER EXPOSURE LIMIT(S) USED: n/a |

OSHA PERMISSIBLE EXPOSURE LIMIT: Not established

OTHER EXPOSURE LIMIT USED Not established

| | |
|---|---|
| EMERGENCY AND FIRST AID PROCEDURES | Remove from exposure. Remove contaminated clothing. Persons developing serious hypersensitivity reactions must receive immediate medical attention. Upon eye or skin contact, flush affected area with copious quantities of water. Obtain medical attention. If not breathing give artificial respiration. If breathing is difficult give oxygen. |
| 1. INHALATION | May cause irritation of respiratory tract. Remove to fresh air. |
| 2. EYES | May cause irritation. Flush with copious quantities of water. |
| 3. SKIN | May cause irritation. Flush with copious quantities of water. |
| 4. INGESTION | May cause irritation. Flush out mouth with water. |

## SECTION 6 - SPECIAL PROTECTION INFORMATION

| | |
|---|---|
| RESPIRATORY PROTECTION (SPECIFY TYPE) | NIOSH approved respirator |
| VENTILATION | Adequate |
| LOCAL EXHAUST | Recommended |
| MECHANICAL (GENERAL) | Recommended |
| OTHER | n/a |
| PROTECTIVE GLOVES | Impervious |
| EYE PROTECTION | Safety goggles |
| OTHER PROTECTIVE CLOTHING OR EQUIPMENT | Protect exposed skin, appropriate laboratory apparel |

n/a = not applicable

ORIGINAL

Nafcillin Sodium
Common Name

Cat # 45000

MATERIAL SAFETY DATA SHEET
UNITED STATES PHARMACOPEIAL CONVENTION, INC.

## SECTION 7 - SPECIAL PRECAUTIONS AND SPILL/LEAK PROCEDURES

| | |
|---|---|
| PRECAUTIONS TO BE TAKEN IN HANDLING AND STORAGE | Store in tight container as defined in the United States Pharmacopeia. This material should be handled and stored per label and other instructions to ensure product integrity. |
| OTHER PRECAUTIONS | Avoid contact with eyes, skin or clothing. Avoid breathing dust or mist. Use with adequate dust control. Wash thoroughly after handling. Wear fresh clothing daily. Wash contaminated clothing before reuse. Do not permit eating, drinking or smoking near material. |
| STEPS TO BE TAKEN IN CASE MATERIAL IS SPILLED OR RELEASED | Wear approved respirator and chemically compatible gloves. Vacuum or sweep up spillage. Avoid dust. Place spillage in appropriate container for waste disposal. Wash contaminated clothing before reuse. Ventilate area and wash spill site. |
| WASTE DISPOSAL METHODS | Dispose of waste in accordance with all applicable Federal, State and local laws. |

NOTICE: The information contained herein is applicable solely to the chemical substance when used as a USP Reference Standard and does not relate to an other use of the substance described. Its use is intended by persons having technical skill and at their own discretion and risk. The information has been developed by USP staff from sources considered reliable but has not been independently verified by the USP. Therefore, the USP Convention cannot guarantee the accuracy of the information in these sources nor should the statements contained herein be considered an official expression. NO REPRESENTATION OR WARRANTY, EXPRESS OR IMPLIED, INCLUDING THE WARRANTIES OF MERCHANTABILITY AND FITNESS FOR A PARTICULAR PURPOSE is made with respect to the information contained herein.

ATTENTION:
This Product is Sold as a Reference Standard for Use In Chemical Analysis Not For Human Consumption.

---

n/a = not applicable

# MATERIAL SAFETY DATA SHEET

CAS: 69-53-4

ORIGINAL

## SECTION I

MANUFACTURER'S NAME: Wyeth Laboratories, Inc.

EMERGENCY TELEPHONE NO.: 215-688-4400

ADDRESS (Number, Street, City, State & Zip Code): King of Prussia Road, Radnor, PA 19087

CHEMICAL NAME AND SYNONYMS: 4-THIA-1-AZABICYCLO(3.2.0)HEPTANE-2-CARBOXYLIC ACID,6-(2-AMINO-2-PHENYLACETAMIDO)-3,3-DIMETHYL-7-OXO-,D-(-)-; WY-5103; AMPICILLIN ACID; 6-(D(-)-ALPHA-AMINOPHENYLACETAMIDO)PENICILLANIC ACID; AMPICILLIN A;D AMPICILLI AMPICILLIN ANHYDRATE

TRADE NAME AND SYNONYMS: Ampicillin; Omnipen

MOLECULAR WEIGHT: 349.27

CHEMICAL FAMILY: Antibiotic

FORMULA: $C_{16}H_{19}N_3O_4S$

PURPOSE FOR CONTINUING INVESTIGATION:

## SECTION II HAZARDOUS INGREDIENTS OR MIXTURES

Pure Substance

## SECTION III PHYSICAL DATA

| | | | |
|---|---|---|---|
| BOILING POINT (°F) | | SPECIFIC GRAVITY ($H_2O$ = 1) | |
| VAPOR PRESSURE (mm Hg) | | PERCENT VOLATILE BY VOLUME (%) | |
| VAPOR DENSITY (AIR = 1) | | EVAPORATION RATE | |
| SOLUBILITY IN WATER | Sparingly | MELTING POINT | (decomposes) 199-202°C |
| APPEARANCE AND ODOR | Crystals | | |

## SECTION IV FIRE AND EXPLOSION HAZARD DATA

| FLASH POINT (Method used) | FLAMMABLE LIMITS | Lel | Uel |
|---|---|---|---|
| Unknown | | | |

EXTINGUISHING MEDIA:

SPECIAL FIRE FIGHTING PROCEDURES:

UNUSUAL FIRE AND EXPLOSION HAZARDS:

## SECTION V HEALTH HAZARD DATA

THRESHOLD LIMIT VALUE: IPR (MUS) $LD_{50}$ = 3250 mg/kg; IVN (MUS) $LD_{50}$ = 4990 mg/kg; (IPR (MUS) $LD_{50}$ = 3480 mg/kg (SALT)

EFFECTS OF OVEREXPOSURE:

Nausea, Vomiting, Diarrhea, Anemia; Reversible blood and Lymphatic changes; Hypersensitivity reactions may occur: Rashes, Urticaria, Dermatitis, and Anaphylaxis which can lead to difficult breathing, convulsions, coma, and death. These reactions are usually associated with drug treatment.

EMERGENCY AND FIRST AID PROCEDURES:

Remove person from area. Treat symptomatically. Rashes may be controlled with antihistamines. Serious anaphylatic reactions require the immediate use of epinephrine, oxygen and intravenous steroids. If ingested, induce vomiting or conduct gastric lavage if gag reflex is lost.

## SECTION VI REACTIVITY DATA

ORIGINAL

| STABILITY | CONDITIONS TO AVOID |
|---|---|
| ☐ UNSTABLE ☒ STABLE | |

INCOMPATIBILITY (Materials to avoid)

HAZARDOUS DECOMPOSITION PRODUCTS

| HAZARDOUS POLYMERIZATION | CONDITIONS TO AVOID |
|---|---|
| ☐ MAY OCCUR ☒ MAY NOT OCCUR | |

## SECTION VII SPILL OR LEAK PROCEDURES

STEPS TO BE TAKEN IN CASE MATERIAL IS RELEASED OR SPILLED

Avoid creating dust. Vacuum up spill.

WASTE DISPOSAL METHOD

Approved landfill.

## SECTION VIII SPECIAL PROTECTION INFORMATION

RESPIRATORY PROTECTION (Specific Type)

NIOSH approved dust respirator recommended in areas with high concentration of dust.

| VENTILATION | SPECIAL |
|---|---|
| ☒ LOCAL EXHAUST | |
| ☒ MECHANICAL (General) | OTHER |

Local exhaust at points of dust creation.

| PROTECTIVE GLOVES | EYE PROTECTION |
|---|---|
| ast impervious gloves recommended. | |

OTHER PROTECTIVE EQUIPMENT.

## SECTION IX SPECIAL PRECAUTIONS

PRECAUTIONS TO BE TAKEN IN HANDLING AND STORING

Avoid dust creation.

OTHER PRECAUTIONS

Persons with a history of allergy to penicillin should avoid all exposure.

## SECTION X ANIMAL PHARMACOLOGY

CARDIOVASCULAR

No effects on CV in therapeutic range.

CENTRAL NERVOUS

Convulsions after overdose.

ENDOCRINE

No effect.

EXCRETORY

Excreted in bile - feces.

GASTROINTESTINAL

Undergoes enterohepatic circulation after rapid absorption.

REPRODUCTIVE

effect.

RESPIRATORY

None except some stimulation after overdose.

For more information refer to:

Other: platelet dysfunction - bleeding (after high doses)

Goodman & Gilman: The Pharmacological Basis of Therapeutics, 6th Ed. 1980, p. 1126 (Chapter 50)

Penicillin G Benzathine ORIGINAL
Common Name
Cat # 50200
Units package size: 200 mg

# MATERIAL SAFETY DATA SHEET
## UNITED STATES PHARMACOPEIAL CONVENTION, INC.

address:
12601 Twinbrook Parkway
Rockville, MD 20852 USA

emergency and information
telephone calls:
(301) 881-0666

William M. Heller
Responsible Party

10-10-85
date prepared

WARNING STATEMENT
WARNING! REFERENCE STANDARD; NOT FOR HUMAN CONSUMPTION; AVOID INGESTION, INHALATION, SKIN CONTACT. FOR CHEMICAL TEST AND ASSAY USE ONLY.

### SECTION 1 - IDENTITY

| | |
|---|---|
| COMMON NAME | Penicillin G Benzathine |
| SYNONYMS | n/a |
| CAS NUMBER | 1538-09-6 (anhydrous) |
| RTEC NUMBER | XH9425000 |
| CHEMICAL NAME | 4-Thia-1-azabicyclo [3.2.0]heptane-2-carboxylic acid, 3,3-dimethyl-7-oxo-6-[(phenylacetyl)amino]-, [2S-(2a,5a,6b)]-, compound with N,N bis (phenylmethyl)1,2-ethanediamine (2:1) tetrahydrate |
| CHEMICAL FAMILY | Penicillin |
| FORMULA | (C16H18N2O4S)2. C16H20N2. 4H2O |

### SECTION 2 - HAZARDOUS INGREDIENTS

| | NAME | PERCENT | THRESHOLD LIMIT VALUE (UNITS) |
|---|---|---|---|
| PRINCIPAL HAZARDOUS COMPONENT(S)/[Chemical & Common name(s)] | Penicillin G Benzathine | Pure Material | Not Established |

### SECTION 3 - PHYSICAL AND CHEMICAL CHARACTERISTICS (Fire & Explosion Data)

| | |
|---|---|
| BOILING POINT | n/a |
| SPECIFIC GRAVITY (H2O = 1) | n/a |
| VAPOR PRESSURE (mm Hg) | n/a |

n/a = not applicable

Penicillin G Benzathine
Common Name
Cat # 50200

ORIGINAL

MATERIAL SAFETY DATA SHEET
UNITED STATES PHARMACOPEIAL CONVENTION, INC.

| | |
|---|---|
| PERCENT VOLATILE BY VOLUME (%) | n/a |
| VAPOR DENSITY (AIR = 1) | n/a |
| EVAPORATION RATE | n/a |
| SOLUBILITY IN WATER | Very soluble |
| REACTIVITY IN WATER | n/a |
| APPEARANCE AND ODOR | Colorless or white crystals or white crystalline powder, odorless |
| FLASH POINT | n/a |
| FLAMMABLE LIMITS IN AIR % BY VOLUME | LOWER n/a UPPER n/a |
| EXTINGUISHER MEDIA | Water spray, dry chemical, carbon dioxide or foam as appropriate for surrounding fire and materials. |
| AUTO-IGNITION TEMPERATURE | n/a |
| SPECIAL FIRE FIGHTING PROCEDURES | As with all fires, evacuate personnel to safe area. Firefighters should use self-contained breathing equipment and protective clothing. |
| UNUSUAL FIRE AND EXPLOSION HAZARDS | This material is assumed to be combustible. As with all dry powders it is advisable to ground mechanical equipment in contact with dry material to dissipate the potential buildup of static electricity. When heated to decomposition material emits toxic fumes. Emits toxic fumes under fire condition. |

## SECTION 4 - PHYSICAL HAZARDS

| | |
|---|---|
| STABILITY | ( ) Unstable ( X ) Stable |
| CONDITIONS TO AVOID | Material is stable from a safety point of view. |
| INCOMPATABILITY (MATERIALS TO AVOID) | n/a |
| HAZARDOUS DECOMPOSITION PRODUCTS | When heated to decomposition material emits toxic fumes. Emits toxic fumes under fire conditions. |
| HAZARDOUS POLYMERIZATION | ( ) May Occur ( X ) Will Not Occur |

n.a = not applicable

ORIGINAL

Penicillin G Benzathine
Common Name
Cat # 50200

MATERIAL SAFETY DATA SHEET
UNITED STATES PHARMACOPEIAL CONVENTION, INC.

SECTION 5 - HEALTH HAZARDS

| | |
|---|---|
| THRESHOLD LIMIT VALUE | None established |
| SIGNS AND SYMPTOMS OF OVEREXPOSURE | Possible allergic reaction to dust if inhaled, ingested or in contact with skin. Reported symptoms include skin rash and labored breathing. |
| ACUTE | Eye, skin and/or respiratory tract irritation, skin rash, hives, itching, wheezing, nausea, chills, fever |
| CHRONIC | Possible hypersensitization |
| PRECAUTIONS TO CONSIDER | Persons developing hypersensitivity (anaphylactic) reactions must receive immediate medical attention. Harmful if swallowed, inhaled or absorbed through skin. Individuals with previous history of significant allergy (especially to antibiotics) and/or asthma should avoid potential exposure to this material. Individuals hypersensitive to one penicillin may be hypersensitive to other penicillins also. Individuals hypersensitive to cephalosporins, griseofulvin, or penicillamine may be hypersensitive to penicillins also. Allergic reactions are more common than frank toxicity. Anaphylactic shock is rare, but can follow a one-microgram test dose. It is managed by epinephrine. Accelerated (one to 72 hours) and late urticarial reactions are much more common. Material may be irritating to mucous membranes and respiratory tract. As a general rule, when handling USP Reference Standards avoid all contact and inhalation of dust, fumes, mist, and/or vapors associated with the material. Keep container tightly closed and use with adequate ventilation; wash thoroughly after handling. Individuals working with chemicals should consider all chemicals to be potentially hazardous even if their individual hazards may be uncharacterized or unknown. |
| MEDICAL CONDITIONS AGGRAVATED BY EXPOSURE | Hypersensitivity to material |

| | | | |
|---|---|---|---|
| CHEMICAL LISTED AS CARCINOGEN OR POTENTIAL CARCINOGEN | NATIONAL TOXICOLOGY PROGRAM | ( ) Yes | ( X ) No |
| | I.A.R.C. Monographs | ( ) Yes | ( X ) No |
| | OSHA | ( ) Yes | ( X ) No |
| | OTHER | | n/a |

n.a = not applicable

ORIGINAL

Penicillin G Benzathine
Common Name

Cat # 50200

MATERIAL SAFETY DATA SHEET
UNITED STATES PHARMACOPEIAL CONVENTION, INC.

| | |
|---|---|
| ACGIH TLV: | n/a |
| OTHER EXPOSURE LIMIT(S) USED: | n/a |

| | |
|---|---|
| OSHA PERMISSIBLE EXPOSURE LIMIT: | Not established |
| OTHER EXPOSURE LIMIT USED | Not established |
| EMERGENCY AND FIRST AID PROCEDURES | Remove from exposure. Remove contaminated clothing. Persons developing serious hypersensitivity reactions must receive immediate medical attention. Upon eye or skin contact, flush affected area with copious quantities of water. Obtain medical attention. If not breathing give artificial respiration. If breathing is difficult give oxygen. |
| 1. INHALATION | May cause irritation of respiratory tract. Remove to fresh air. |
| 2. EYES | May cause irritation. Flush with copious quantities of water. |
| 3. SKIN | May cause irritation. Flush with copious quantities of water. |
| INGESTION | May cause irritation. Flush out mouth with water. |

## SECTION 6 - SPECIAL PROTECTION INFORMATION

| | |
|---|---|
| RESPIRATORY PROTECTION (SPECIFY TYPE) | NIOSH approved respirator |
| VENTILATION | Adequate |
| LOCAL EXHAUST | Recommended |
| MECHANICAL (GENERAL) | Recommended |
| OTHER | n/a |
| PROTECTIVE GLOVES | Impervious |
| EYE PROTECTION | Safety goggles |
| OTHER PROTECTIVE CLOTHING OR EQUIPMENT | Protect exposed skin, appropriate laboratory apparel |

n.a = not applicable

Penicillin G Benzathine
Common Name
Cat # 50200

ORIGINAL

MATERIAL SAFETY DATA SHEET
UNITED STATES PHARMACOPEIAL CONVENTION, INC.

## SECTION 7 - SPECIAL PRECAUTIONS AND SPILL/LEAK PROCEDURES

**PRECAUTIONS TO BE TAKEN IN HANDLING AND STORAGE** Store in tight container as defined in the United States Pharmacopeia. This material should be handled and stored per label and other instructions to ensure product integrity.

**OTHER PRECAUTIONS** Avoid contact with eyes, skin or clothing. Avoid breathing dust or mist. Use with adequate dust control. Wash thoroughly after handling. Wear fresh clothing daily. Wash contaminated clothing before reuse. Do not permit eating, drinking or smoking near material.

**STEPS TO BE TAKEN IN CASE MATERIAL IS SPILLED OR RELEASED** Wear approved respirator and chemically compatible gloves. Vacuum or sweep up spillage. Avoid dust. Place spillage in appropriate container for waste disposal. Wash contaminated clothing before reuse. Ventilate area and wash spill site.

**WASTE DISPOSAL METHODS** Dispose of waste in accordance with all applicable Federal, State and local laws.

NOTICE: The information contained herein is applicable solely to the chemical substance when used as a USP Reference Standard and does not relate to any other use of the substance described. Its use is intended by persons having technical skill and at their own discretion and risk. The information has been developed by USP staff from sources considered reliable but has not been independently verified by the USP. Therefore, the USP Convention cannot guarantee the accuracy of the information in these sources nor should the statements contained herein be considered an official expression. NO REPRESENTATION OR WARRANTY, EXPRESS OR IMPLIED, INCLUDING THE WARRANTIES OF MERCHANTABILITY AND FITNESS FOR A PARTICULAR PURPOSE is made with respect to the information contained herein.

ATTENTION:
This Product is Sold as a Reference Standard for Use In Chemical Analysis
Not For Human Consumption.

n.a. = not applicable

ORIGINAL

# MATERIAL SAFETY DATA SHEET

## Penicillin G Procaine

Wyeth-Ayerst Laboratories
P.O. Box 8299
Philadelphia, PA 19101
215-688-4400

## SECTION I - IDENTITY

| | |
|---|---|
| CHEMICAL OR COMMON NAME: | Penicillin G Procaine |
| SYNONYMS: | N/A |
| FORMULA: | $C_{16}H_{18}N_2O_4S$ |
| CAS NUMBER: | 61-33-6 |
| CHEMICAL FAMILY: | Penicillin |

## SECTION II - HAZARDOUS COMPONENTS

| COMPONENT | CAS NO. | % | TLV |
|---|---|---|---|
| Pure Compound | | | |

## SECTION III - PHYSICAL AND CHEMICAL DATA

| | |
|---|---|
| BOILING POINT: | N/A |
| MELTING POINT: | N/A |
| SPECIFIC GRAVITY (H2O=1): | N/A |
| VAPOR PRESSURE (mm Hg): | N/A |
| PERCENT VOLATILE BY VOLUME: | N/A |
| VAPOR DENSITY (AIR=1): | N/A |
| EVAPORATION RATE: | N/A |
| SOLUBILITY IN WATER: | 6.8 mg/ml at 28°C |
| APPEARANCE AND ODOR: | White crystalline powder |
| STABILITY: | ( ) Unstable (X) Stable |
| HAZARDOUS POLYMERIZATION: | ( ) May Occur (X) Will Not Occur |
| CONDITIONS/MATERIALS TO AVOID: | Stable in regard to safety concerns |
| HAZARDOUS DECOMPOSITION PRODUCTS: | N/A |

ORIGINAL

## SECTION IV - FIRE AND EXPLOSION DATA

| | |
|---|---|
| FLASH POINT: | N/A |
| FLAMMABLE LIMITS: | LEL - N/A UEL - N/A |
| AUTO-IGNITION TEMPERATURE: | N/A |
| EXTINGUISHING MEDIA: | All media are acceptable. Choose as appropriate for surrounding fire and materials. |
| SPECIAL FIRE FIGHTING PROCEDURES: | Wear protective clothing and self-contained breathing apparatus. |
| UNUSUAL FIRE AND EXPLOSION HAZARDS: | Dry material is assumed to be combustible. Avoid accumulations and keep away from ignition sources. |

## SECTION V - TOXICOLOGY DATA

| | |
|---|---|
| LD50 (ORAL RAT): | N/A |
| LD50 (DERMAL RABBIT): | N/A |
| LD50 (IVN-MUS): | 329 mg/kg |
| LD50 (ICE-MUS): | 5700 ug/kg |
| LC50 (RAT): | N/A |
| IRRITATION: | N/A |
| LISTED AS CARCINOGEN OR POTENTIAL CARCINOGEN: | OSHA ( ) Yes (X) No<br>NTP ( ) Yes (X) No<br>IARC ( ) Yes (X) No |
| TARGET ORGANS: | None |

## SECTION VI - HEALTH HAZARD DATA

| | |
|---|---|
| THRESHOLD LIMIT VALUE: | N/A |
| THERAPEUTIC DOSE: | 300,000 - 4.8 million units |

ROUTES OF ABSORPTION: (N/A) DERMAL (X) INHALATION (X) INGESTION

| | |
|---|---|
| EFFECTS OF EXPOSURE: | Pharmacological active drug used to treat infections caused by microorganisms. Hypersensitivity reactions: skin rashes, urticaria, serum sickness, anaphylaxis. |

ORIGINAL

| | |
|---|---|
| MEDICAL CONDITIONS AGGRAVATED BY EXPOSURE: | Hypersensitivity |
| SUBSTANCES PRODUCING ADDITIVE EFFECTS: | Sensitivity to multiple allergens. |

## SECTION VII - EMERGENCY FIRST AID

| | |
|---|---|
| EYE CONTACT: | Flush with copious amounts of water. Separate eyelids with fingers while flushing. See physician if redness or irritation develops. |
| SKIN CONTACT: | Wash with copious amounts of water. Remove contaminated clothing. See physician if redness or irritation develops. |
| INHALATION: | Remove to fresh air. Call physician and treat symptoms. |
| INGESTION: | Flush out mouth with water. Call physician and treat symptoms. |
| NOTE: | Anaphylactic reactions require immediate emergency treatment with epinephrine, oxygen and intravenous corticosteroid as directed. |

## SECTION VIII - SPECIAL PROTECTION INFORMATION

| | |
|---|---|
| VENTILATION: | Use in well ventilated area. Use additional local exhaust ventilation at all points of aerosol generation to prevent airborne concentrations and accumulation. |
| RESPIRATORY PROTECTION: | Use NIOSH approved respirator during operations producing aerosols as required to avoid inhalation. |
| EYE PROTECTION: | Recommended |

| | |
|---|---|
| PROTECTIVE GLOVES: | Recommended |
| PROTECTIVE CLOTHING: | Use as required to prevent skin contact. |
| WORK/HYGIENIC PRACTICES: | Persons with a history of allergy to penicillin should avoid exposure. |

## SECTION IX - STORAGE AND HANDLING

| | |
|---|---|
| STORAGE/HANDLING PRECAUTIONS: | No special storage precautions are required for safety. Handle and store per label and other instructions to maintain product integrity. |
| OTHER PRECAUTIONS: | Avoid contact and inhalation. Use with adequate ventilation and avoid generating airborne particulates. Wash thoroughly after handling. Do not eat, drink or smoke near material. |

## SECTION X - SPILL AND LEAK PROCEDURES

| | |
|---|---|
| STEPS FOR RELEASE OF SPILL: | Clean up small spills with a damp towel. Vacuum or sweep/mop up larger spills. Avoid creating airborne material. Place in an appropriate container for waste disposal. Wash with water and ventilate area. Wear protective clothing. |
| WASTE DISPOSAL: | Incinerate in an approved incinerator or take to an approved land disposal site. Follow all Local, State and Federal regulations. |

==========

N/A = NOT APPLICABLE OR NOT AVAILABLE

DATE ISSUED: February 9, 1988 ( ) New (X) Revised

CHEMISTRY: R. Rees, Ph.D.

TOXICOLOGY: M. Hite, Ph.D.

MEDICAL: S. J. Rogers, Pharm D.

SAFETY: D. VonKaenel

OTHER: N/A

==========

PHYSICIANS SHOULD CONSULT THE PACKAGE INSERT FOR PRESCRIBING INFORMATION. THE DATA IN THIS MATERIAL SAFETY DATA SHEET RELATES TO THE SPECIFIC MATERIAL DESIGNATED HEREIN AND DOES NOT RELATE TO USE IN COMBINATION WITH ANY OTHER MATERIAL OR IN ANY PROCESS. THE INFORMATION SET FORTH HEREIN IS BASED ON TECHNICAL DATA THAT WYETH BELIEVES TO BE RELIABLE. IT IS INTENDED FOR USE BY PERSONS HAVING TECHNICAL SKILL AND AT THEIR OWN DISCRETION AND RISK. SINCE CONDITIONS OF USE ARE OUTSIDE OUR CONTROL, WE MAKE NO WARRANTIES, EXPRESS OR IMPLIED, AND ASSUME NO LIABILITY IN CONNECTION WITH ANY USE OF THIS INFORMATION. NOTHING HEREIN IS TO BE TAKEN AS A LICENSE TO OPERATE OR A RECOMMENDATION TO INFRINGE ANY PATENTS.

INVOICE #: 127064 CUST. #: 6135 CUSTOMER: WYETH LABORATORIES, INC.
Page 1 of 5

ORIGINAL

Pentobarbital
Common Name
Cat # 50700
Units package size: 200 mg

# MATERIAL SAFETY DATA SHEET
## UNITED STATES PHARMACOPEIAL CONVENTION, INC.

address:
12601 Twinbrook Parkway
Rockville, MD 20852 USA

emergency and information
telephone calls:
(301) 881-0666

William M. Heller
Responsible Party

11-14-86
date prepared

WARNING STATEMENT
WARNING! *REFERENCE STANDARD; NOT FOR HUMAN CONSUMPTION; AVOID INGESTION, INHALATION, SKIN CONTACT. FOR CHEMICAL TEST AND ASSAY USE ONLY.*

## SECTION 1 - IDENTITY

| | |
|---|---|
| COMMON NAME | Pentobarbital |
| SYNONYMS | n/a |
| CAS NUMBER | 76-74-4 |
| RTECS NUMBER | CQ5775000 |
| CHEMICAL NAME | 5-Ethyl-5-(1-methylbutyl)barbituric acid |
| CHEMICAL FAMILY | Sedative, anticonvulsant |
| FORMULA | C11H18N2O3 |

## SECTION 2 - HAZARDOUS INGREDIENTS

| NAME | PERCENT | THRESHOLD LIMIT VALUE (UNITS) |
|---|---|---|
| PRINCIPAL HAZARDOUS COMPONENT(S)/[Chemical & Common name(s)] | Pentobarbital Pure Material | Not Established |

## SECTION 3 - PHYSICAL AND CHEMICAL CHARACTERISTICS (Fire & Explosion Data)

| | |
|---|---|
| BOILING POINT | n/a |
| SPECIFIC GRAVITY (H2O = 1) | n/a |
| VAPOR PRESSURE (mm Hg) | n/a |

n/a = not applicable

Pentobarbital
Common Name
Cat # 50700

ORIGINAL

MATERIAL SAFETY DATA SHEET
UNITED STATES PHARMACOPEIAL CONVENTION, INC.

| | |
|---|---|
| PERCENT VOLATILE BY VOLUME (%) | n/a |
| VAPOR DENSITY (AIR = 1) | n/a |
| EVAPORATION RATE | n/a |
| SOLUBILITY IN WATER | Very slightly soluble |
| REACTIVITY IN WATER | n/a |
| APPEARANCE AND ODOR | White to practically white, fine powder, practically odorless |
| FLASH POINT | n/a |
| FLAMMABLE LIMITS IN AIR % BY VOLUME | LOWER n/a UPPER n/a |
| EXTINGUISHER MEDIA | Water spray, dry chemical, carbon dioxide or foam as appropriate for surrounding fire and materials. |
| AUTO-IGNITION TEMPERATURE | n/a |
| SPECIAL FIRE FIGHTING PROCEDURES | As with all fires, evacuate personnel to safe area. Firefighters should use self-contained breathing equipment and protective clothing. |
| UNUSUAL FIRE AND EXPLOSION HAZARDS | This material is assumed to be combustible. As with all dry powders it is advisable to ground mechanical equipment in contact with dry material to dissipate the potential buildup of static electricity. When heated to decomposition material emits toxic fumes. Emits toxic fumes under fire conditions. |

SECTION 4 - PHYSICAL HAZARDS

| | |
|---|---|
| STABILITY | ( ) Unstable ( X ) Stable |
| CONDITIONS TO AVOID | Material is stable from a safety point of view. |
| INCOMPATABILITY (MATERIALS TO AVOID) | n/a |
| HAZARDOUS DECOMPOSITION PRODUCTS | When heated to decomposition material emits toxic fumes. Emits toxic fumes under fire conditions. |
| HAZARDOUS POLYMERIZATION | ( ) May Occur ( X ) Will Not Occur |

n/a = not applicable

Pentobarbital
Common Name
Cat # 50700

ORIGINAL

MATERIAL SAFETY DATA SHEET
UNITED STATES PHARMACOPEIAL CONVENTION, INC.

SECTION 5 - HEALTH HAZARDS

| | |
|---|---|
| THRESHOLD LIMIT VALUE | None established |
| SIGNS AND SYMPTOMS OF OVEREXPOSURE | Possible allergic reaction to dust if inhaled, ingested or in contact with skin. In acute barbiturate overdosage, CNS and respiratory depression may progress to Cheyne-Stokes respiration, areflexia, slight constriction of the pupils (in severe toxicity, pupils may be dilated), oliguria, tachycardia, lowered body temperature, and coma. Typical shock syndrome (apnea, circulatory collapse, respiratory arrest, and death) may occur. |
| ACUTE | Eye, skin and/or respiratory tract irritation, confusion, drowsiness (severe), shortness of breath or unusually slow or troubled breathing, slurred speech, staggering, unusually slow heartbeat, unusual movements of the eyes, weakness (severe) |
| CHRONIC | Possible hypersensitization, confusion (severe), poor judgment, trouble in sleeping, unusual irritability (continuing) |
| PRECAUTIONS TO CONSIDER | Persons developing hypersensitivity (anaphylactic) reactions must receive immediate medical attention. Material may be irritating to mucous membranes and respiratory tract. As a general rule, when handling USP Reference Standards avoid all contact and inhalation of dust, fumes, mists, and/or vapors associated with the material. Keep container tightly closed and use with adequate ventilation; wash thoroughly after handling. Individuals working with chemicals should consider all chemicals to be potentially hazardous even if their individual hazards may be uncharacterized or unknown. Persons hypersensitive to one of the barbiturates may be hypersensitive to other barbiturates also. |
| MEDICAL CONDITIONS AGGRAVATED BY EXPOSURE | Hypersensitivity to material |

| | | | |
|---|---|---|---|
| CHEMICAL LISTED AS CARCINOGEN OR POTENTIAL CARCINOGEN | NATIONAL TOXICOLOGY PROGRAM | ( ) Yes | ( X ) No |
| | I.A.R.C. Monographs | ( ) Yes | ( X ) No |
| | OSHA | ( ) Yes | ( X ) No |
| | OTHER | | n/a |

n/a = not applicable

ORIGINAL

Pentobarbital
Common Name
Cat # 50700

MATERIAL SAFETY DATA SHEET
UNITED STATES PHARMACOPEIAL CONVENTION, INC.

| | | | |
|---|---|---|---|
| | ACGIH TLV: | n/a | OTHER EXPOSURE LIMIT(S) USED: n/a |

OSHA PERMISSIBLE EXPOSURE LIMIT: Not established

OTHER EXPOSURE LIMIT USED Not established

EMERGENCY AND FIRST AID PROCEDURES: Remove from exposure. Remove contaminated clothing. Persons developing serious hypersensitivity reactions must receive immediate medical attention. Upon eye or skin contact, flush affected area with copious quantities of water. Obtain medical attention. If person is awake and loss of consciousness is not imminent, give by mouth syrup of ipecac or a slurry of activated charcoal. Keep person warm and maintain respiration.

1. INHALATION: May cause irritation of respiratory tract. Remove to fresh air.
2. EYES: May cause irritation. Flush with copious quantities of water.
3. SKIN: May cause irritation. Flush with copious quantities of water.
4. INGESTION: May cause irritation. Flush out mouth with water.

## SECTION 6 - SPECIAL PROTECTION INFORMATION

| | |
|---|---|
| RESPIRATORY PROTECTION (SPECIFY TYPE) | NIOSH approved respirator |
| VENTILATION | Adequate |
| LOCAL EXHAUST | Recommended |
| MECHANICAL (GENERAL) | Recommended |
| OTHER | n/a |
| PROTECTIVE GLOVES | Impervious rubber |
| EYE PROTECTION | Safety goggles |
| OTHER PROTECTIVE CLOTHING OR EQUIPMENT | Protect exposed skin, appropriate laboratory apparel |

= not applicable

ORIGINAL

Pentobarbital
Common Name

Cat # 50700

MATERIAL SAFETY DATA SHEET
UNITED STATES PHARMACOPEIAL CONVENTION, INC.

## SECTION 7 - SPECIAL PRECAUTIONS AND SPILL/LEAK PROCEDURES

**PRECAUTIONS TO BE TAKEN IN HANDLING AND STORAGE** Store in tight container as defined in the United States Pharmacopeia. This material should be handled and stored per label and other instructions to ensure product integrity.

**OTHER PRECAUTIONS** Avoid contact with eyes, skin or clothing. Avoid breathing dust or mist. Use with adequate dust control. Wash thoroughly after handling. Wear fresh clothing daily. Wash contaminated clothing before reuse. Do not permit eating, drinking or smoking near material.

**STEPS TO BE TAKEN IN CASE MATERIAL IS SPILLED OR RELEASED** Wear approved respirator and chemically compatible gloves. Vacuum or sweep up spillage. Avoid dust. Place spillage in appropriate container for waste disposal. Wash contaminated clothing before reuse. Ventilate area and wash spill site.

**WASTE DISPOSAL METHODS** Dispose of waste in accordance with all applicable Federal, State and local laws.

NOTICE: The information contained herein is applicable solely to the chemical substance when used as a USP Reference Standard and does not relate to any other use of the substance described. Its use is intended by persons having technical skill and at their own discretion and risk. The information has been developed by USP staff from sources considered reliable but has not been independently verified by the USP. Therefore, the USP Convention cannot guarantee the accuracy of the information in these sources nor should the statements contained herein be considered an official expression. NO REPRESENTATION OR WARRANTY, EXPRESS OR IMPLIED, INCLUDING THE WARRANTIES OF MERCHANTABILITY AND FITNESS FOR A PARTICULAR PURPOSE is made with respect to the information contained herein.

ATTENTION:
This Product is Sold as a Reference Standard for Use In Chemical Analysis Not For Human Consumption.

---

NA = not applicable

# MATERIAL SAFETY DATA SHEET

CAS: 60-87-7

ORIGINAL

## SECTION I

MANUFACTURER'S NAME: Wyeth Laboratories, Inc.

EMERGENCY TELEPHONE NO.: 215-688-4400

ADDRESS (Number, Street, City, State & Zip Code): King of Prussia Road & Lancaster Avenue, Radnor, PA 19087

CHEMICAL NAME AND SYNONYMS: N,N, ∝-trimethyl-10H-phenothiazine-ID-ethanamide; 10-(2-dimethylaminopropyl) phenothiazine; WY 590 for HCl salt

TRADE NAME AND SYNONYMS: Promethazine; Phenergan

MOLECULAR WEIGHT: 284.41

CHEMICAL FAMILY: Phenothiazine

FORMULA: $C_{17}H_{20}N_2S$

PURPOSE FOR CONTINUING INVESTIGATION

H HEALTH 2
F FLAMMABILITY 1
R REACTIVITY 0
PERSONAL PROTECTION X
NC-L503R © 1985 NPCA

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## SECTION II HAZARDOUS INGREDIENTS OR MIXTURES

## SECTION III PHYSICAL DATA

| | | | |
|---|---|---|---|
| BOILING POINT °C | 190-192 | SPECIFIC GRAVITY ($H_2O$ = 1) | |
| VAPOR PRESSURE (mm Hg) | | PERCENT VOLATILE BY VOLUME (%) | |
| VAPOR DENSITY (AIR = 1) | | EVAPORATION RATE | |
| SOLUBILITY IN WATER | insoluble | MELTING POINT | 60°C |

APPEARANCE AND ODOR: White to faint yellow crystalline powder; practically odorless

## SECTION IV FIRE AND EXPLOSION HAZARD DATA

| FLASH POINT (Method used) | FLAMMABLE LIMITS | Lel | Uel |
|---|---|---|---|
| | | | |

EXTINGUISHING MEDIA

SPECIAL FIRE FIGHTING PROCEDURES

UNUSUAL FIRE AND EXPLOSION HAZARDS

## SECTION V HEALTH HAZARD DATA

THRESHOLD LIMIT VALUE

orl-mus $LD_{50}$: 326 mg/kg; orl-rbt $LD_{50}$: 580 mg/kg

EFFECTS OF OVEREXPOSURE

Drowsiness, dizziness, fatigue, nervousness, incoordination, euphoria, tinnitus, urticaria, photosensitivity, dryness of mouth. May cause contact dermatitis. Currently tested by NTP as of January 1983.

EMERGENCY AND FIRST AID PROCEDURES

Remove to fresh air and call physician. Treat symptomatically.

Ingestion: gastric lavage. Skin or eye contact: Rinse area with copious amounts of water.

ORIGINAL

## SECTION VI REACTIVITY DATA

| STABILITY | CONDITIONS TO AVOID |
|---|---|
| ☐ UNSTABLE ☒ STABLE | |

INCOMPATIBILITY (Materials to avoid)

HAZARDOUS DECOMPOSITION PRODUCTS

| HAZARDOUS POLYMERIZATION | CONDITIONS TO AVOID |
|---|---|
| ☐ MAY OCCUR ☒ MAY NOT OCCUR | |

## SECTION VII SPILL OR LEAK PROCEDURES

STEPS TO BE TAKEN IN CASE MATERIAL IS RELEASED OR SPILLED

Carefully sweep up or vacuum. Avoid creating dust.

WASTE DISPOSAL METHOD

Approved landfill.

## SECTION VIII SPECIAL PROTECTION INFORMATION

RESPIRATORY PROTECTION (Specific Type)

NIOSH approved dust respirator in high dust concentrations.

| VENTILATION | SPECIAL |
|---|---|
| ☒ LOCAL EXHAUST At points of dust | |
| ☒ MECHANICAL (General) generation | OTHER |

| PROTECTIVE GLOVES | EYE PROTECTION |
|---|---|
| Plastic or latex gloves | Safety glasses/goggles |

OTHER PROTECTIVE EQUIPMENT:

## SECTION IX SPECIAL PRECAUTIONS

PRECAUTIONS TO BE TAKEN IN HANDLING AND STORING

Avoid breathing or direct contact. Follow good personal hygiene practices.

OTHER PRECAUTIONS

## SECTION X ANIMAL PHARMACOLOGY

CARDIOVASCULAR

Transient fall in blood pressure after parenteral injection.

CENTRAL NERVOUS Stimulation and, high doses, depression; blocks chemo-receptive trigger center

ENDOCRINE

EXCRETORY

GASTROINTESTINAL

Reduces intestinal motility

REPRODUCTIVE

RESPIRATORY

Antagonizes bronchoconstriction to histamine and acehyldroline

For more information refer to:

Goodman & Gilman, The Pharmacological Basis of Therapeutics, 6th Edition, Chapter 26.

# MATERIAL SAFETY DATA SHEET

ORIGINAL

GANES CHEMICALS, INC.
1114 Avenue of the Americas
New York, NY 10036

For Additional Information Telephone 1(212)391-2580

Date of Issue: January 2, 1986

## IDENTIFICATION

Product Name: PHENOBARBITAL SODIUM

CAS Registry Number: 57-30-7 Ganes Code Number: 4

RTECS Accession Number: CQ7000000

Chemical Names:

1. 2,4,6(1H,3H,5H)-Pyrimidinetrione, 5-ethyl-5-phenyl-, monosodium salt.

2. Sodium 5-ethyl-5-phenylbarbiturate.

Synonyms:

1. Luminal Sodium.

2. Gardenal Sodium.

3. Soluble Phenobarbutal.

4. Sodium Phenobarbitone.

## SUMMARY

**Phenobarbital Sodium is a physiologically active drug substance. It is toxic if ingested in larger than therapeutic quantities. The carcinogenic determination by IARC is animal positive. Wear a dust respirator, goggles, and gloves when handling; use only with adequate ventilation. Wash exposed skin with soap and water. Sweep up spilled material and flush spill area with water. Save swept up material for recovery. If the material cannot be recovered, incineration is the recommended disposal procedure.**

## INGREDIENTS

Not less than 98.5% Phenobarbital Sodium.

## PHYSICAL DATA

| | |
|---|---|
| Description: | White, odorless, flaky crystals or crystalline granules or powder. |
| Melting Range: | Not applicable. |
| Water Solubility: | Very soluble. |
| Molecular Weight: | 254.22 |
| Molecular Formula: | $C_{12}H_{11}N_2NaO_3$ |

## FIRE, EXPLOSION, AND REACTIVITY DATA

### Stability

Stable.

### Hazardous Decomposition Products

When heated to decomposition, toxic fumes such as nitrogen oxides and sodium oxides are emitted.

### Extinguishing Media

Foam, carbon dioxide, dry chemical.

### Special Fire Fighting Instructions

Isolate hazard and evacuate confined areas. Stay upwind; avoid smoke and fumes. Use water spray to wet containers. If smoke and fumes cannot be avoided, wear a chemical-proof suit with hood and breathing air supply. Fight fire from maximum distance.

## HEALTH DATA

### Toxicity

| | | | | |
|---|---|---|---|---|
| Oral | - Man | $TD_{Lo}$: | 36 | mg/kg |
| Oral | - Rat | $LD_{50}$: | 660 | mg/kg |
| Oral | - Mouse | $LD_{50}$: | 200 | mg/kg |
| Oral | - Cat | $LD_{50}$: | 175 | mg/kg |
| Oral | - Rabbit | $LD_{50}$: | 150 | mg/kg |
| Subcutaneous | - Rat | $LD_{50}$: | 200 | mg/kg |
| Subcutaneous | - Mouse | $LD_{50}$: | 230 | mg/kg |
| Intraperitoneal | - Rat | $LD_{50}$: | 190 | mg/kg |
| Intraperitoneal | - Mouse | $LD_{50}$: | 235 | mg/kg |
| Intraperitoneal | - Rabbit | $LD_{50}$: | 150 | mg/kg |
| Intraperitoneal | - Guinea Pig | $LD_{Lo}$: | 150 | mg/kg |
| Intravenous | - Rat | $LD_{50}$: | 83 | mg/kg |
| Intravenous | - Mouse | $LD_{50}$: | 238 | mg/kg |
| Intravenous | - Rabbit | $LD_{50}$: | 185 | mg/kg |
| Oral | - Rat | $TD_{Lo}$: | 25 | g/kg/2Y-C |
| Oral | - Rat | $TD_{Lo}$: | 3623 | mg/kg (1-21D preg) |
| Oral | - Mouse | $TD_{Lo}$: | 660 | mg/kg (6-16D preg) |
| Oral | - Mouse | $TD_{Lo}$: | 1650 | mg/kg (6-16D preg) |
| Subcutaneous | - Rat | $TD_{Lo}$: | 520 | mg/kg (9-21D preg) |
| Subcutaneous | - Rat | $TD_{Lo}$: | 1040 | mg/kg (9-21D preg) |
| Subcutaneous | - Mouse | $TD_{Lo}$: | 120 | mg/kg (16-21D preg) |
| Subcutaneous | - Mouse | $TD_{Lo}$: | 240 | mg/kg (16-21D preg) |
| Subcutaneous | - Mouse | $TD_{Lo}$: | 200 | mg/kg (4-8D preg) |
| Intraperitoneal | - Rat | $TD_{Lo}$: | 160 | mg/kg (9-21D preg) |
| Intraperitoneal | - Rat | $TD_{Lo}$: | 40800 | mcg/kg (1D preg) |
| Intravenous | - Domestic Animal | $TD_{Lo}$: | 4 | mg/kg (18W preg) |

### Toxicity Classification

Highly toxic by oral, subcutaneous, intraperitoneal, and intravenous administration (Reference 1).

### Explosure Effects

Can cause sleepiness; mental confusion; unsteadiness; coma with slow, shallow respiration; flaccid muscles; hypotension; cyanosis; hypothermia or hyperthermia; and absent reflexes.

First Aid

If respirations are shallow or if cyanosis is present, give artificial respiration or, if indicated, oxygen. Keep air passage open. Call a physician.

If swallowed, induce vomiting with 2 tablespoonful of ipecac syrup or 2 glasses of water or dilute milk followed by tickling the back of the patients throat with a finger or the blunt end of a spoon, fork, or knife. Following induced vomiting give one to two tablespoonfuls of activated charcoal in a glass of water. Call a physician.

Carcinogenicity

The IARC monograph for phenobarbital sodium lists the carcinogenic determination as animal positive (Reference 4).

Exposure Limits

Exposure limits for Phenobarbital Sodium have not been established by OSHA or ACGIH.

Safety Precautions

Avoid breathing the dust.
Avoid contact with eye and skin.
Wash thoroughly after handling.

PROTECTION INFORMATION

Use with adequate ventilation to prevent dust build up.
Wear a dust respirator, gloves, and goggles when handling to prevent inhaling dust, eye contact, and skin contact.

ORIGINAL

SPILL AND DISPOSAL INFORMATION

Shovel large quantities of spilled material into drums. Sweep up the spill area and save the material for recovery. Flush the spill area with detergent and water. For further information regarding recovery of contaminated material, call Ganes Chemicals, Inc., 1-(212)391-2580.

If the material cannot be recovered, the preferred method of disposal is incineration in a facility which complies with all Federal, State, and local regulations.

SHIPPING INFORMATION

DOT

Not regulated.

IATA

Not regulated.

IMO

Not regulated.

REFERENCES

1. Dangerous Properties of Industrial Materials, N. Irving Sax, Sixth Edition, Van Nostrand Reinhold Company, Inc.,135 West 50th Street, New York, NY 10020, page 2438.

2. Registry of Toxic Effects of Chemical Substances, U.S. Department of Health and Human Services, Public Health Service,Center for Disease Control, National Institute for Occupational Safety and Health [NIOSH Pub. No. 83-107], Volume I, page 496.

3. Threshold Limit Values for Chemical Substances and Physical Agents in the Workroom Environment with Intended Changes, American Conference of Governmental Industrial Hygienists, Cincinnati, OH 45211.

4. IARC Monographs on the Evaluation of the Carcinogenic Risk of Chemicals to Man, Geneva: World Health Organization, International Agency for Research on Cancer, 49 Sheridan Street, Albany, New York, 1977, Volume 13, page 159.

5. Occupational Health Guidelines for Chemical Hazards, U.S. Department of Health and Human Services, Center for Disease Control, National Institute for Occupational Safety and Health [NIOSH Pub. No. 81-123].

6. IATA Dangerous Goods Regulations, International Air Transport Association, Montreal, Quebec, Canada, 27th Edition.

7. International Maritime Dangerous Goods Code, International Maritime Organization, London, England, 1982.

8. Code of Federal Regulations, Title 49, Parts 100 to 177.

9. Code of Federal Regulations, Title 29, Part 1910, Subpart Z.

10. Handbook of Poisoning, Robert H. Dreisbach, 11th Edition, 1983, Lange Medical Publications, Los Altos, California 94022.

11. Handbook of Emergency Toxicology, Sidney Kaye, Fourth Edition, 1980.

12. Martindale-The Extra Pharmacopoeia, 28th Edition, Edited by James E. F. Reynolds, 1982, Pharmacentical Press, London, England.

13. American Hospital Formulary Service-Drug Information 84, American Society of Hospital Pharmacists, Bethesda, Maryland, 1984.

14. AMA Drug Evaluations, 5th Edition, American Medical Association, W.B. Saunders Company, Philadelphia, PA., 1983.

# MATERIAL SAFETY DATA SHEET

## 1. CHEMICAL PRODUCT AND COMPANY IDENTIFICATION

**MDL INFORMATION SYSTEMS, INC.**
**1281 Murfreesboro Road, Suite 300**
**Nashville, TN 37217-2423**

**1-615-366-2000**

**EMERGENCY TELEPHONE NUMBER**
**1-800-424-9300 (NORTH AMERICA)**
**1-703-527-3887 (INTERNATIONAL)**

**SUBSTANCE: AMPICILLIN TRIHYDRATE** POLYFLEX

**TRADE NAMES/SYNONYMS:**
4-THIA-1-AZABICYCLO(3.2.0)HEPTANE-2-CARBOXYLIC ACID, 6-((AMINOPHENYL-ACETYL)AMINO)-3,3-DIMETHYL-7-OXO-, TRIHYDRATE, (2S-(2ALPHA,5ALPHA,6 BETA (S*)))-; 4-THIA-1-AZABICYCLO(3.2.0)HEPTANE-2-CARBOXYLIC ACID, 6-(2-AMINO-2-PHENYLACETAMIDO)-3,3-DIMETHYL-7-OXO-, TRIHYDRATE, D-(-)-; (2S-(2ALPHA,5ALPHA,6BETA(S*)))-6-((AMINOPHENYLACETYL)AMINO)-3,3- DIMETHYL-7-OXO-4-THIA-1-AZABICYCLO(3.2.0)HEPTANE-2-CARBOXYLIC ACID, TRIHYDRATE; D-(-)-6-(2-AMINO-2-PHENYLACETAMIDO)-3,3-DIMETHYL-7-OXO-4-THIA-1- AZABICYCLO(3.2.0) HEPTANE-2-CARBOXYLIC ACID, TRIHYDRATE; RO-AMPEN; POLYCILLIN; ALPHA-AMINOBENZYLPENICILLIN TRIHYDRATE; ACILLIN; MOREPEN; PENSYN; PRINCILLIN; PRINCIPEN; C16H25N3O7S; OHS60934; RTECS XH8425000

**CHEMICAL FAMILY:** antibiotic/antiseptic

**CREATION DATE:** May 04 1987
**REVISION DATE:** Jun 16 2005

## 2. COMPOSITION, INFORMATION ON INGREDIENTS

**COMPONENT:** AMPICILLIN TRIHYDRATE
**CAS NUMBER:** 7177-48-2
**EC NUMBER:** Not assigned.
**PERCENTAGE:** 100

## 3. HAZARDS IDENTIFICATION

**NFPA RATINGS (SCALE 0-4):** HEALTH=0 FIRE=1 REACTIVITY=0

**EMERGENCY OVERVIEW:**
**COLOR:** white
**PHYSICAL FORM:** crystalline powder
**ODOR:** faint odor
**MAJOR HEALTH HAZARDS:** allergic reactions
**PHYSICAL HAZARDS:** Dust/air mixtures may ignite or explode.

**POTENTIAL HEALTH EFFECTS:**
**INHALATION:**
**SHORT TERM EXPOSURE:** allergic reactions, asthma
**LONG TERM EXPOSURE:** no information on significant adverse effects
**SKIN CONTACT:**
**SHORT TERM EXPOSURE:** irritation, allergic reactions, asthma
**LONG TERM EXPOSURE:** same as effects reported in short term exposure
**EYE CONTACT:**
**SHORT TERM EXPOSURE:** irritation, allergic reactions
**LONG TERM EXPOSURE:** no information on significant adverse effects
**INGESTION:**
**SHORT TERM EXPOSURE:** allergic reactions, diarrhea, blood disorders
**LONG TERM EXPOSURE:** rash, nausea, vomiting, stomach pain, chest pain, wheezing, asthma, dizziness, bluish skin color, lung congestion, convulsions

**CARCINOGEN STATUS:**
**OSHA:** No
**NTP:** No
**IARC:** No

## 4. FIRST AID MEASURES

**INHALATION:** If adverse effects occur, remove to uncontaminated area. Give artificial respiration if not breathing. Get immediate medical attention.

**SKIN CONTACT:** Wash skin with soap and water for at least 15 minutes while removing contaminated clothing and shoes. Get medical attention, if needed. Thoroughly clean and dry contaminated clothing and shoes before reuse.

**EYE CONTACT:** Flush eyes with plenty of water for at least 15 minutes. Then get immediate medical attention.

**INGESTION:** If swallowed, drink plenty of water, do NOT induce vomiting. Get immediate medical attention. Induce vomiting only at the instructions of a physician. Do not give anything by mouth to unconscious or convulsive person.

**ANTIDOTE:** penicillinase. For anaphylactic reactions, epinephrine; steroids, intravenous.

**NOTE TO PHYSICIAN:** For ingestion, consider gastric lavage, activated charcoal slurry and catharsis.

## 5. FIRE FIGHTING MEASURES

**FIRE AND EXPLOSION HAZARDS:** Slight fire hazard. Dust/air mixtures may ignite or explode.

**EXTINGUISHING MEDIA:** regular dry chemical, carbon dioxide, water, regular foam

Large fires: Use regular foam or flood with fine water spray.

**FIRE FIGHTING:** Move container from fire area if it can be done without risk. Do not scatter spilled material with high-pressure water streams. Dike for later disposal. Use extinguishing agents appropriate for surrounding fire. Avoid inhalation of material or combustion by-products. Stay upwind and keep out of low areas.

## 6. ACCIDENTAL RELEASE MEASURES

**OCCUPATIONAL RELEASE:**
Collect spilled material in appropriate container for disposal. Keep out of water supplies and sewers. Keep unnecessary people away, isolate hazard area and deny entry.

## 7. HANDLING AND STORAGE

**STORAGE:** Store and handle in accordance with all current regulations and standards. Keep separated from incompatible substances. Store in a cool, dry place. Store in a tightly closed container.

## 8. EXPOSURE CONTROLS, PERSONAL PROTECTION

**EXPOSURE LIMITS:**
**AMPICILLIN TRIHYDRATE:**
No occupational exposure limits established.

**VENTILATION:** Provide local exhaust ventilation system. Ensure compliance with applicable exposure limits.

**EYE PROTECTION:** Wear splash resistant safety goggles with a faceshield. Provide an emergency eye wash fountain and quick drench shower in the immediate work area.

**CLOTHING:** Wear appropriate chemical resistant clothing.

**GLOVES:** Wear appropriate chemical resistant gloves.

**RESPIRATOR:** Under conditions of frequent use or heavy exposure, respiratory protection may be needed. Respiratory protection is ranked in order from minimum to maximum. Consider warning properties before use.
Any supplied-air respirator with a full facepiece that is operated in a pressure-demand or other positive-pressure mode.
Any self-contained breathing apparatus that has a full facepiece and is operated in a pressure-demand or other positive-pressure mode.
**For Unknown Concentrations or Immediately Dangerous to Life or Health -**
Any supplied-air respirator with full facepiece and operated in a pressure-demand or other positive-pressure mode in combination with a separate escape supply.
Any self-contained breathing apparatus with a full facepiece.

## 9. PHYSICAL AND CHEMICAL PROPERTIES

**PHYSICAL STATE:** solid
**COLOR:** white
**PHYSICAL FORM:** crystalline powder
**ODOR:** faint odor
**MOLECULAR WEIGHT:** 403.50
**MOLECULAR FORMULA:** C16-H19-N3-O4-S.3(H2O)
**BOILING POINT:** Not applicable
**MELTING POINT:** 388-392 F (198-200 C)
**VAPOR PRESSURE:** Not applicable
**VAPOR DENSITY:** Not applicable
**SPECIFIC GRAVITY:** Not available
**WATER SOLUBILITY:** slightly soluble
**PH:** 5.0-7.0
**VOLATILITY:** Not applicable
**ODOR THRESHOLD:** Not available
**EVAPORATION RATE:** Not applicable
**COEFFICIENT OF WATER/OIL DISTRIBUTION:** Not available
**SOLVENT SOLUBILITY:**
**Soluble:** absolute alcohol, methanol
**Insoluble:** benzene, carbon tetrachloride, chloroform, ether

## 10. STABILITY AND REACTIVITY

**REACTIVITY:** Stable at normal temperatures and pressure.

**CONDITIONS TO AVOID:** Avoid heat, flames, sparks and other sources of ignition. Avoid contact with incompatible materials.

**INCOMPATIBILITIES:** oxidizing materials

AMPICILLIN TRIHYDRATE:
OXIDIZERS (STRONG): Fire and explosion hazard.

**HAZARDOUS DECOMPOSITION:**
Thermal decomposition products: oxides of carbon, nitrogen, sulfur

**POLYMERIZATION:** Will not polymerize.

## 11. TOXICOLOGICAL INFORMATION

**AMPICILLIN TRIHYDRATE:**
**TOXICITY DATA:**
10 gm/kg oral-rat LD50; 15200 mg/kg oral-mouse LD50; 33600 mg/kg/14 day(s) intermittent oral-rat TDLo; 5 mg/m3/5 hour(s)-17 week(s) intermittent inhalation-rat TCLo; 33600 mg/kg/14 day(s) intermittent oral-mouse TDLo; 7350 mg/kg/3 week(s) intermittent oral-mouse TDLo; 17.2 gm/kg/7

week(s) intermittent oral-mouse TDLo; 2450 mg/kg/1 week(s) intermittent oral-mouse TDLo; 4900 mg/kg/2 week(s) intermittent oral-mouse TDLo; 63.7 gm/kg/26 week(s) intermittent oral-mouse TDLo; 546 gm/kg/26 week(s) intermittent oral-mouse TDLo

**CARCINOGEN STATUS:** IARC: Human Inadequate Evidence, Animal Limited Evidence, Group 3 Ampicillin has been associated with skin and lung cancer, one case of lymphoproliferative disease, and one case of Kaposi's sarcoma in humans. Oral administration in animals has resulted in increased incidences of mononuclear-cell leukemia and of phaeochromocytomas of the adrenal medulla in male rats and a slight increase in the incidence of benign lung tumors in female mice.

**ACUTE TOXICITY LEVEL:**
Slightly Toxic: ingestion

**TARGET ORGANS:** immune system (sensitizer)

**MEDICAL CONDITIONS AGGRAVATED BY EXPOSURE:** immune system disorders or allergies

**TUMORIGENIC DATA:**
386250 mg/kg oral-rat TDLo/103 week(s) intermittent

**REPRODUCTIVE EFFECTS DATA:**
1500 mg/kg oral-rat TDLo 6-11 day(s) pregnant female continuous; 2800 mg/kg oral-rat TDLo 7-13 day (s) pregnant female continuous; 9100 mg/kg oral-mouse TDLo 7-13 day(s) pregnant female continuous; 28 gm/kg oral-mouse TDLo 7-13 day(s) pregnant female continuous

**ADDITIONAL DATA:** May cross the placenta. May be excreted in breast milk. Interactions with drugs may occur. May cross react with similar compounds.

**HEALTH EFFECTS:**
**INHALATION:**
AMPICILLIN: See information on penicillins. In addition, irritation of the upper respiratory tract has been reported.

**ACUTE EXPOSURE:**
PENICILLINS: On rare occasions, anaphylactic shock, as detailed in ingestion, has resulted from the inhalation of penicillins in sensitive individuals. Bronchoconstriction and asthma may occur.

**CHRONIC EXPOSURE:**
PENICILLINS: Repeated exposure may result in sensitization.

**SKIN CONTACT:**
AMPICILLIN: See information on penicillins. In addition, skin irritation has been reported.

**ACUTE EXPOSURE:**
PENICILLINS: Topical administration of penicillins has produced serious hypersensitivity reactions such as angioedema with marked swelling of the lips, tongue, face and periorbital tissues, asthmatic breathing and giant hives. Intradermal instillation of very small quantities in skin testing has resulted in anaphylaxis and death in sensitized individuals.

**CHRONIC EXPOSURE:**
PENICILLINS: Repeated contact may result in sensitization. Allergic contact dermatitis has been reported from handling penicillins or the repeated topical application of penicillin ointments.

**EYE CONTACT:**
AMPICILLIN: See information on penicillins. In addition, eye irritation has been reported.

**ACUTE EXPOSURE:**
PENICILLINS: The penicillins have had a high incidence of contact allergic reactions when applied

topically.

**CHRONIC EXPOSURE:**
PENICILLINS: Repeated contact may result in sensitization and polyarthralgia ecchymosis.

**INGESTION:**
AMPICILLIN: Chronic administration of ampicillin and ampicillin trihydrate to experimental animals produced altered sense of taste and smell, diarrhea, aplastic anemia, agranulocytosis and pancytopenia. Increased salivation, excessive urination, chromodacryorrhea, decreased activity, inflammation, ulceration, hyperkeratosis and acanthosis of the forestomach, cytoplasmic vacuolization of the liver, inflammation of the prostate, C-cell hyperplasia of the thyroid gland, mononuclear cell leukemia, and benign and malignant pheochromocytomas of the adrenal medulla have been reported. An increase in the frequency of chromosomal aberrations in human lymphocytes has been reported. Reproductive effects have been reported in animals.

**ACUTE EXPOSURE:**
PENICILLINS: In non-allergic persons, even large doses are generally non-toxic. Hypersensitivity reactions, immediate and/or delayed, may occur in individuals without known prior exposure and may be due to unrecognized exposure to penicillin in the environment. These reactions may include anaphylaxis, angioedema and serum sickness type reactions; symptoms are described in chronic exposure.

**CHRONIC EXPOSURE:**
PENICILLINS: Repeated ingestion of penicillins may cause nausea with or without vomiting, epigastric distress, mild to severe diarrhea, sore or dry mouth, sore or black hairy tongue. Pseudomembranous colitis has been reported rarely. The most severe immediate hypersensitivity reaction is anaphylactic shock, which although usually associated with parenteral administration, has occurred with ingestion. Symptoms, which can occur within minutes, may include urticaria, purpuric skin lesions, localized edema, extreme weakness, dizziness, nausea, vomiting, diarrhea, abdominal pain and cramps, bronchoconstriction with severe asthma, chest pain, severe hypotension, cyanosis, circulatory collapse, pulmonary edema, convulsions and death in respiratory failure. Some individuals may have angioedema with marked swelling of the lips, tongue, face and periorbital tissues, asthmatic breathing and giant hives. Other immediate reactions may include laryngeal edema, laryngospasm and bronchospasm. Delayed reactions may include various skin rashes, ranging from maculopapular to exfoliative dermatitis, and serum sickness type reactions. Symptoms of the latter may include chills with or without fever, rash, leukopenia, purpura, arthralgia or arthritis, myalgia, generalized edema, malaise, mental changes, lymphadenopathy, splenomegaly, ECG changes indicative of myocarditis and albuminuria and hematuria. Interstitial nephritis has been reported. Other signs of hypersensitivity may include wheezing, flushing of the skin, pruritus, vasculitis of the skin or other organs, positive coomb's reactions, infrequently with hemolytic anemia, neutropenia, thrombocytopenia, eosinophilia, granulocytopenia and anemia. Infrequent effects may include jaundice, liver necrosis, central nervous system toxicity and neuropathy.

## 12. ECOLOGICAL INFORMATION

Not available

## 13. DISPOSAL CONSIDERATIONS

Dispose in accordance with all applicable regulations.

## 14. TRANSPORT INFORMATION

**U.S. DEPARTMENT OF TRANSPORTATION:** No classification assigned.

**CANADIAN TRANSPORTATION OF DANGEROUS GOODS:** No classification assigned.

**LAND TRANSPORT ADR:** No classification assigned.

**LAND TRANSPORT RID:** No classification assigned.

**AIR TRANSPORT IATA:** No classification assigned.

**AIR TRANSPORT ICAO:** No classification assigned.

**MARITIME TRANSPORT IMDG:** No classification assigned.

## 15. REGULATORY INFORMATION

**U.S. REGULATIONS:**
**CERCLA SECTIONS 102a/103 HAZARDOUS SUBSTANCES (40 CFR 302.4):** Not regulated.

**SARA TITLE III SECTION 302 EXTREMELY HAZARDOUS SUBSTANCES (40 CFR 355.30):** Not regulated.

**SARA TITLE III SECTION 304 EXTREMELY HAZARDOUS SUBSTANCES (40 CFR 355.40):** Not regulated.

**SARA TITLE III SARA SECTIONS 311/312 HAZARDOUS CATEGORIES (40 CFR 370.21):**
ACUTE: Yes
CHRONIC: Yes
FIRE: No
REACTIVE: No
SUDDEN RELEASE: No

**SARA TITLE III SECTION 313 (40 CFR 372.65):** Not regulated.

**OSHA PROCESS SAFETY (29CFR1910.119):** Not regulated.

**STATE REGULATIONS:**
**California Proposition 65:** Not regulated.

**CANADIAN REGULATIONS:**
**WHMIS CLASSIFICATION:** Not determined.

**EUROPEAN REGULATIONS:**
**EC CLASSIFICATION (CALCULATED):**

| | |
|---|---|
| Xn | Harmful |

**DANGER/HAZARD SYMBOL:**

Xn

**EC RISK AND SAFETY PHRASES:**

| | |
|---|---|
| R 42 | May cause sensitization by inhalation. |
| R 43 | May cause sensitization by skin contact. |
| R 64 | May cause harm to breastfed babies. |
| S 2 | Keep out of the reach of children. |
| S 24 | Avoid contact with skin. |
| S 46 | If swallowed, seek medical advice immediately and show this container or label. |

**GERMAN REGULATIONS:**
**WATER HAZARD CLASS (WGK):**
**STATE OF CLASSIFICATION:** Annex 3
**CLASSIFICATION UNDER HAZARD TO WATER:** 1

**NATIONAL INVENTORY STATUS:**
**U.S. INVENTORY (TSCA):** Not listed on inventory.

**TSCA 12(b) EXPORT NOTIFICATION:** Not listed.

## 16. OTHER INFORMATION

**MSDS SUMMARY OF CHANGES**
15. REGULATORY INFORMATION

#11 Non-Official Exhibit #16 #7

INVOICE #: 127064 CUST. #: 6135 CUSTOMER: WYETH LABORATORIES, INC.


Secobarbital
Common Name
Cat # 61100
Units package size: 200 mg

# MATERIAL SAFETY DATA SHEET
## UNITED STATES PHARMACOPEIAL CONVENTION, INC.

address:
12601 Twinbrook Parkway
Rockville, MD 20852 USA

emergency and information
telephone calls:
(301) 881-0666

William M. Heller — 11-14-86
Responsible Party — date prepared

WARNING STATEMENT
WARNING! REFERENCE STANDARD; NOT FOR HUMAN CONSUMPTION; AVOID INGESTION, INHALATION, SKIN CONTACT. FOR CHEMICAL TEST AND ASSAY USE ONLY.

## SECTION 1 - IDENTITY

| | |
|---|---|
| COMMON NAME | Secobarbital |
| SYNONYMS | n/a |
| CAS NUMBER | 76-73-3 |
| RTECS NUMBER | CP9450000 |
| CHEMICAL NAME | 5-Allyl-5-(1-methylbutyl) barbituric acid |
| CHEMICAL FAMILY | Barbiturate |
| FORMULA | C12H18N2O3 |

## SECTION 2 - HAZARDOUS INGREDIENTS

| | NAME | PERCENT | THRESHOLD LIMIT VALUE (UNITS) |
|---|---|---|---|
| PRINCIPAL HAZARDOUS COMPONENT(S)/[Chemical & Common name(s)] | Secobarbital | Pure Material | Not Established |

## SECTION 3 - PHYSICAL AND CHEMICAL CHARACTERISTICS (Fire & Explosion Data)

| | |
|---|---|
| BOILING POINT | n/a |
| SPECIFIC GRAVITY (H2O = 1) | n/a |
| VAPOR PRESSURE (mm Hg) | n/a |

n/a = not applicable

ORIGINAL

Secobarbital
Common Name
Cat # 61100

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UNITED STATES PHARMACOPEIAL CONVENTION, INC.

| | |
|---|---|
| PERCENT VOLATILE BY VOLUME (%) | n/a |
| VAPOR DENSITY (AIR = 1) | n/a |
| EVAPORATION RATE* | n/a |
| SOLUBILITY IN WATER | Very slightly soluble |
| REACTIVITY IN WATER | n/a |
| APPEARANCE AND ODOR | White, amorphous or crystalline powder, odorless |
| FLASH POINT | n/a |
| FLAMMABLE LIMITS IN AIR % BY VOLUME | LOWER n/a UPPER n/a |
| EXTINGUISHER MEDIA | Water spray, dry chemical, carbon dioxide or foam as appropriate for surrounding fire and materials. |
| AUTO-IGNITION TEMPERATURE | n/a |
| SPECIAL FIRE FIGHTING PROCEDURES | As with all fires, evacuate personnel to safe area. Firefighters should use self-contained breathing equipment and protective clothing. |
| UNUSUAL FIRE AND EXPLOSION HAZARDS | This material is assumed to be combustible. As with all dry powders it is advisable to ground mechanical equipment in contact with dry material to dissipate the potential buildup of static electricity. When heated to decomposition material emits toxic fumes. Emits toxic fumes under fire conditions. |

## SECTION 4 - PHYSICAL HAZARDS

| | |
|---|---|
| STABILITY | ( ) Unstable ( X ) Stable |
| CONDITIONS TO AVOID | Material is stable from a safety point of view. |
| INCOMPATABILITY (MATERIALS TO AVOID) | n/a |
| HAZARDOUS DECOMPOSITION PRODUCTS | When heated to decomposition material emits toxic fumes. Emits toxic fumes under fire conditions. |
| HAZARDOUS POLYMERIZATION | ( ) May Occur ( X ) Will Not Occur |

n/a = not applicable

Secobarbital
Common Name
Cat # 61100

ORIGINAL

MATERIAL SAFETY DATA SHEET
UNITED STATES PHARMACOPEIAL CONVENTION, INC.

SECTION 5 - HEALTH HAZARDS

| | |
|---|---|
| THRESHOLD LIMIT VALUE | None established |
| SIGNS AND SYMPTOMS OF OVEREXPOSURE | [LD50: 116 mg/Kg intraperitoneal-mouse] Possible allergic reaction to dust if inhaled, ingested or in contact with skin. In acute barbiturate overdosage, CNS and respiratory depression may progress to Cheyne-Stokes respiration, areflexia, slight constriction of the pupils (in severe toxicity, pupils may be dilated), oliguria, tachycardia, lowered body temperature, and coma. Typical shock syndrome (apnea, circulatory collapse, respiratory arrest, and death) may occur. |
| ACUTE | Eye, skin and/or respiratory tract irritation, signs of acute toxicity, confusion, severe drowsiness, shortness of breath or unusually slow or troubled breathing, slurred speech, staggering, unusually slow heartbeat, unusual movements of the eyes, severe weakness |
| CHRONIC | Possible hypersensitization, signs of chronic toxicity, severe confusion, poor judgment, trouble in sleeping, continuing unusual irritability |
| PRECAUTIONS TO CONSIDER | Persons developing hypersensitivity (anaphylactic) reactions must receive immediate medical attention. Material may be irritating to mucous membranes and respiratory tract. As a general rule, when handling USP Reference Standards avoid all contact and inhalation of dust, fumes, mists, and/or vapors associated with the material. Keep container tightly closed and use with adequate ventilation; wash thoroughly after handling. Individuals working with chemicals should consider all chemicals to be potentially hazardous even if their individual hazards may be uncharacterized or unknown. Persons hypersensitive to one barbiturate may be hypersensitive to other barbiturates also. |
| MEDICAL CONDITIONS AGGRAVATED BY EXPOSURE | Hypersensitivity to material |

| | | | |
|---|---|---|---|
| CHEMICAL LISTED AS CARCINOGEN OR POTENTIAL CARCINOGEN | NATIONAL TOXICOLOGY PROGRAM | ( ) Yes | ( X ) No |
| | I.A.R.C. Monographs | ( ) Yes | ( X ) No |
| | OSHA | ( ) Yes | ( X ) No |
| | OTHER | | n/a |

n/a = not applicable

ORIGINAL

Secobarbital
Common Name

Cat # 61100

MATERIAL SAFETY DATA SHEET
UNITED STATES PHARMACOPEIAL CONVENTION, INC.

| | |
|---|---|
| ACGIH TLV: | n/a |
| OTHER EXPOSURE LIMIT(S) USED: | n/a |

| | |
|---|---|
| OSHA PERMISSIBLE EXPOSURE LIMIT: | Not established |
| OTHER EXPOSURE LIMIT USED | Not established |

| | |
|---|---|
| EMERGENCY AND FIRST AID PROCEDURES | Remove from exposure. Remove contaminated clothing. Persons developing serious hypersensitivity reactions must receive immediate medical attention. Upon eye or skin contact, flush affected area with copious quantities of water. Obtain medical attention. Treatment of barbiturate overdosage is primarily supportive. An adequate airway should be maintained, with assisted respiration and administration of oxygen as needed. Vital signs and fluid balance should be monitored. |
| 1. INHALATION | May cause irritation of respiratory tract. Remove to fresh air. |
| 2. EYES | May cause irritation. Flush with copious quantities of water. |
| SKIN | May cause irritation. Flush with copious quantities of water. |
| 4. INGESTION | May cause irritation. Flush out mouth with water. |

## SECTION 6 - SPECIAL PROTECTION INFORMATION

| | |
|---|---|
| RESPIRATORY PROTECTION (SPECIFY TYPE) | NIOSH approved respirator |
| VENTILATION | Adequate |
| LOCAL EXHAUST | Recommended |
| MECHANICAL (GENERAL) | Recommended |
| OTHER | n/a |
| PROTECTIVE GLOVES | Impervious Rubber |
| EYE PROTECTION | Safety goggles |
| OTHER PROTECTIVE CLOTHING OR EQUIPMENT | Appropriate laboratory apparel, protect exposed skin |

n/a = not applicable

ORIGINAL

Secobarbital
Common Name

Cat # 61100

MATERIAL SAFETY DATA SHEET
UNITED STATES PHARMACOPEIAL CONVENTION, INC.

## SECTION 7 - SPECIAL PRECAUTIONS AND SPILL/LEAK PROCEDURES

**PRECAUTIONS TO BE TAKEN IN HANDLING AND STORAGE** Store in tight container as defined in the United States Pharmacopeia. This material should be handled and stored per label and other instructions to ensure product integrity.

**OTHER PRECAUTIONS** Avoid contact with eyes, skin or clothing. Avoid breathing dust or mist. Use with adequate dust control. Wash thoroughly after handling. Wear fresh clothing daily. Wash contaminated clothing before reuse. Do not permit eating, drinking or smoking near material.

**STEPS TO BE TAKEN IN CASE MATERIAL IS SPILLED OR RELEASED** Wear approved respirator and chemically compatible gloves. Vacuum or sweep up spillage. Avoid dust. Place spillage in appropriate container for waste disposal. Wash contaminated clothing before reuse. Ventilate area and wash spill site.

**WASTE DISPOSAL METHODS** Dispose of waste in accordance with all applicable Federal, State and local laws.

NOTICE: The information contained herein is applicable solely to the chemical substance when used as a USP Reference Standard and does not relate to any other use of the substance described. Its use is intended by persons having technical skill and at their own discretion and risk. The information has been developed by USP staff from sources considered reliable but has not been independently verified by the USP. Therefore, the USP Convention cannot guarantee the accuracy of the information in these sources nor should the statements contained herein be considered an official expression. NO REPRESENTATION OR WARRANTY, EXPRESS OR IMPLIED, INCLUDING THE WARRANTIES OF MERCHANTABILITY AND FITNESS FOR A PARTICULAR PURPOSE is made with respect to the information contained herein.

ATTENTION:
This Product is Sold as a Reference Standard for Use In Chemical Analysis Not For Human Consumption.

n/a = not applicable

ORIGINAL

# MATERIAL SAFETY DATA SHEET

## 1. CHEMICAL PRODUCT AND COMPANY IDENTIFICATION

**MDL INFORMATION SYSTEMS, INC.**
**1281 Murfreesboro Road, Suite 300**
**Nashville, TN 37217-2423**

**1-615-366-2000**

**EMERGENCY TELEPHONE NUMBER**
**1-800-424-9300 (NORTH AMERICA)**
**1-703-527-3887 (INTERNATIONAL)**

**SUBSTANCE: AMPICILLIN SODIUM**

**TRADE NAMES/SYNONYMS:**
4-THIA-1-AZABICYCLO(3.2.0)HEPTANE-2-CARBOXYLIC ACID, 6-((AMINOPHENYL-ACETYL)AMINO)-3,3-DIMETHYL-7-OXO-, MONOSODIUM SALT, (2S-(2ALPHA, 5ALPHA,6BETA(S*)))-; 4-THIA-1-AZABICYCLO(3.2.0)HEPTANE-2-CARBOXYLIC ACID, 6-(2-AMINO-2- PHENYLACETAMIDO)-3,3-DIMETHYL-7-OXO-, MONOSODIUM SALT, D-(-)-; (2S-(2ALPHA,5ALPHA,6BETA(S*)))-4-THIA-1-AZABICYCLO(3.2.0)HEPTANE-2- CARBOXYLIC ACID, 6-((AMINOPHENYLACETYL)AMINO)-3,3-DIMETHYL-7-OXO- MONOSODIUM SALT; D-(-)-4-THIA-1-AZABICYCLO(3.2.0)HEPTANE-2-CARBOXYLIC ACID,6-(2-AMINO- 2-PHENYLACETAMIDO)-3,3-DIMETHYL-7-OXO-, MONOSODIUM SALT; AMPICILLIN-NA; AMPICILLIN SODIUM SALT; ONMIPEN-N; POLYCILLIN N; SODIUM AMPICILLIN; SODIUM BINOTAL; SODIUM P-50; ALPEN-N; MONOSODIUM AMPICILLIN; C16H18N3NAO4S; OHS01513; RTECS XH8400000

**CHEMICAL FAMILY:** antibiotic/antiseptic

**CREATION DATE:** Jul 13 1990
**REVISION DATE:** Jun 16 2005

## 2. COMPOSITION, INFORMATION ON INGREDIENTS

**COMPONENT:** AMPICILLIN SODIUM
**CAS NUMBER:** 69-52-3
**EC NUMBER (EINECS):** 200-708-1
**PERCENTAGE:** 100.0

## 3. HAZARDS IDENTIFICATION

**NFPA RATINGS (SCALE 0-4):** HEALTH=2 FIRE=1 REACTIVITY=0

**EMERGENCY OVERVIEW:**
**CHANGE IN APPEARANCE:** hygroscopic
**COLOR:** white to off-white
**PHYSICAL FORM:** crystalline powder
**MAJOR HEALTH HAZARDS:** allergic reactions
**PHYSICAL HAZARDS:** Dust/air mixtures may ignite or explode.

**POTENTIAL HEALTH EFFECTS:**
**INHALATION:**
**SHORT TERM EXPOSURE:** irritation, allergic reactions, asthma
**LONG TERM EXPOSURE:** allergic reactions
**SKIN CONTACT:**
**SHORT TERM EXPOSURE:** irritation, allergic reactions, asthma
**LONG TERM EXPOSURE:** same as effects reported in short term exposure
**EYE CONTACT:**
**SHORT TERM EXPOSURE:** irritation, allergic reactions
**LONG TERM EXPOSURE:** allergic reactions
**INGESTION:**
**SHORT TERM EXPOSURE:** allergic reactions
**LONG TERM EXPOSURE:** rash, nausea, vomiting, diarrhea, stomach pain, chest pain, wheezing, asthma, dizziness, bluish skin color, lung congestion, blood disorders, convulsions

**CARCINOGEN STATUS:**
**OSHA:** No
**NTP:** No
**IARC:** No

## 4. FIRST AID MEASURES

**INHALATION:** If adverse effects occur, remove to uncontaminated area. Give artificial respiration if not breathing. Get immediate medical attention.

**SKIN CONTACT:** Wash skin with soap and water for at least 15 minutes while removing contaminated clothing and shoes. Get medical attention, if needed. Thoroughly clean and dry contaminated clothing and shoes before reuse.

**EYE CONTACT:** Flush eyes with plenty of water for at least 15 minutes. Then get immediate medical attention.

**INGESTION:** If swallowed, drink plenty of water, do NOT induce vomiting. Get immediate medical attention. Induce vomiting only at the instructions of a physician. Do not give anything by mouth to unconscious or convulsive person.

**ANTIDOTE:** penicillinase. For anaphylactic reactions, epinephrine; steroids, intravenous.

**NOTE TO PHYSICIAN:** For ingestion, consider gastric lavage, activated charcoal slurry and catharsis.

## 5. FIRE FIGHTING MEASURES

**FIRE AND EXPLOSION HAZARDS:** Slight fire hazard. Dust/air mixtures may ignite or explode.

**EXTINGUISHING MEDIA:** regular dry chemical, carbon dioxide, water, regular foam

Large fires: Use regular foam or flood with fine water spray.

**FIRE FIGHTING:** Move container from fire area if it can be done without risk. Do not scatter spilled material with high-pressure water streams. Dike for later disposal. Use extinguishing agents appropriate for surrounding fire. Avoid inhalation of material or combustion by-products. Stay upwind and keep out of low areas.

## 6. ACCIDENTAL RELEASE MEASURES

**OCCUPATIONAL RELEASE:**
Collect spilled material in appropriate container for disposal. Keep out of water supplies and sewers. Keep unnecessary people away, isolate hazard area and deny entry.

## 7. HANDLING AND STORAGE

**STORAGE:** Store and handle in accordance with all current regulations and standards. Keep separated from incompatible substances.

## 8. EXPOSURE CONTROLS, PERSONAL PROTECTION

**EXPOSURE LIMITS:**
**AMPICILLIN SODIUM:**
No occupational exposure limits established.

**VENTILATION:** Provide local exhaust ventilation system. Ventilation equipment should be explosion-resistant if explosive concentrations of material are present. Ensure compliance with applicable exposure limits.

**EYE PROTECTION:** Wear splash resistant safety goggles. Provide an emergency eye wash fountain and quick drench shower in the immediate work area.

**CLOTHING:** Wear appropriate chemical resistant clothing.

**GLOVES:** Wear appropriate chemical resistant gloves.

**RESPIRATOR:** Under conditions of frequent use or heavy exposure, respiratory protection may be needed. Respiratory protection is ranked in order from minimum to maximum. Consider warning properties before use.
Any dust, mist, and fume respirator.
Any air-purifying respirator with a high-efficiency particulate filter.
Any powered, air-purifying respirator with a dust, mist, and fume filter.
Any powered, air-purifying respirator with a high-efficiency particulate filter.
**For Unknown Concentrations or Immediately Dangerous to Life or Health -**
Any supplied-air respirator with full facepiece and operated in a pressure-demand or other positive-

pressure mode in combination with a separate escape supply.
Any self-contained breathing apparatus with a full facepiece.

## 9. PHYSICAL AND CHEMICAL PROPERTIES

**PHYSICAL STATE:** solid
**COLOR:** white to off-white
**CHANGE IN APPEARANCE:** hygroscopic
**PHYSICAL FORM:** crystalline powder
**ODOR:** Not available
**MOLECULAR WEIGHT:** 371.39
**MOLECULAR FORMULA:** C16-H18-N3-O4-S.NA
**BOILING POINT:** Not applicable
**MELTING POINT:** 419 F (215 C)
**VAPOR PRESSURE:** Not applicable
**VAPOR DENSITY:** Not applicable
**SPECIFIC GRAVITY:** Not available
**WATER SOLUBILITY:** soluble
**PH:** 8.0-10.0 (1% solution)
**VOLATILITY:** Not applicable
**ODOR THRESHOLD:** Not available
**EVAPORATION RATE:** Not applicable
**COEFFICIENT OF WATER/OIL DISTRIBUTION:** Not available
**SOLVENT SOLUBILITY:**
**Soluble:** sodium chloride solution, dextrose solutions

## 10. STABILITY AND REACTIVITY

**REACTIVITY:** Stable at normal temperatures and pressure.

**CONDITIONS TO AVOID:** Avoid heat, flames, sparks and other sources of ignition. Avoid contact with incompatible materials.

**INCOMPATIBILITIES:** oxidizing materials

AMPICILLIN SODIUM:
OXIDIZERS (STRONG): Fire and explosion hazard.

**HAZARDOUS DECOMPOSITION:**
Thermal decomposition products: oxides of carbon, nitrogen, sulfur, sodium

**POLYMERIZATION:** Will not polymerize.

## 11. TOXICOLOGICAL INFORMATION

**AMPICILLIN SODIUM:**
**TOXICITY DATA:**
100 mg/kg/5 day(s) oral-woman TDLo; >5314 mg/kg oral-rat LD50; 7400 mg/kg intraperitoneal-rat

LD50; >5314 mg/kg subcutaneous-rat LD50; >5314 mg/kg oral-mouse LD50; 5700 mg/kg intraperitoneal-mouse LD50; >5314 mg/kg subcutaneous-mouse LD50; 2657 mg/kg intravenous-mouse LDLo; 210 mg/kg/7 day(s) intermittent intramuscular-rat TDLo
**CARCINOGEN STATUS:** IARC: Human Inadequate Evidence, Animal Limited Evidence, Group 3 Ampicillin has been associated with skin and lung cancer, one case of lymphoproliferative disease, and one case of Kaposi's sarcoma in humans. Oral administration in animals has resulted in increased incidences of mononuclear-cell leukemia and phaeochromocytomas of the adrenal medulla in male rats and a slight increase in the incidence of benign lung tumors in female mice.
**ACUTE TOXICITY LEVEL:** Insufficient Data.
**TARGET ORGANS:** immune system (sensitizer)
**MEDICAL CONDITIONS AGGRAVATED BY EXPOSURE:** immune system disorders or allergies, kidney disorders, blood system disorders
**ADDITIONAL DATA:** May cross the placenta. May be excreted in breast milk. Interactions with drugs may occur. May cross react with similar compounds.

**HEALTH EFFECTS:**
**INHALATION:**
AMPICILLIN SODIUM: May cause irritation. See information on penicillins.

**ACUTE EXPOSURE:**
PENICILLINS: On rare occasions, anaphylactic shock, as detailed in ingestion, has resulted from the inhalation of penicillins in sensitive individuals. Bronchoconstriction and asthma may occur.

**CHRONIC EXPOSURE:**
PENICILLINS: Repeated exposure may result in sensitization.

**SKIN CONTACT:**
AMPICILLIN SODIUM: May cause irritation. See information on penicillins.

**ACUTE EXPOSURE:**
PENICILLINS: Topical administration of penicillins has produced serious hypersensitivity reactions such as angioedema with marked swelling of the lips, tongue, face and periorbital tissues, asthmatic breathing and giant hives. Intradermal instillation of very small quantities in skin testing has resulted in anaphylaxis and death in sensitized individuals.

**CHRONIC EXPOSURE:**
PENICILLINS: Repeated contact may result in sensitization. Allergic contact dermatitis has been reported from handling penicillins or the repeated topical application of penicillin ointments.

**EYE CONTACT:**
AMPICILLIN SODIUM: May cause irritation. See information on penicillins.

**ACUTE EXPOSURE:**
PENICILLINS: The penicillins have had a high incidence of contact allergic reactions when applied topically.

**CHRONIC EXPOSURE:**
PENICILLINS: Repeated contact may result in sensitization and polyarthralgia ecchymosis.

**INGESTION:**
AMPICILLIN SODIUM: Administration in animals has resulted in increased incidences of

mononuclear-cell leukemia and phaeochromocytomas of the adrenal medulla in male rats and a slight increase in the incidence of benign lung tumors in female mice. See information on penicillins.

**ACUTE EXPOSURE:**
PENICILLINS: In non-allergic persons, even large doses are generally non-toxic. Hypersensitivity reactions, immediate and/or delayed, may occur in individuals without known prior exposure and may be due to unrecognized exposure to penicillin in the environment. These reactions may include anaphylaxis, angioedema and serum sickness type reactions; symptoms are described in chronic exposure.

**CHRONIC EXPOSURE:**
PENICILLINS: Repeated ingestion of penicillins may cause nausea with or without vomiting, epigastric distress, mild to severe diarrhea, sore or dry mouth, sore or black hairy tongue. Pseudomembranous colitis has been reported rarely. The most severe immediate hypersensitivity reaction is anaphylactic shock, which although usually associated with parenteral administration, has occurred with ingestion. Symptoms, which can occur within minutes, may include urticaria, purpuric skin lesions, localized edema, extreme weakness, dizziness, nausea, vomiting, diarrhea, abdominal pain and cramps, bronchoconstriction with severe asthma, chest pain, severe hypotension, cyanosis, circulatory collapse, pulmonary edema, convulsions and death in respiratory failure. Some individuals may have angioedema with marked swelling of the lips, tongue, face and periorbital tissues, asthmatic breathing and giant hives. Other immediate reactions may include laryngeal edema, laryngospasm and bronchospasm. Delayed reactions may include various skin rashes, ranging from maculopapular to exfoliative dermatitis, and serum sickness type reactions. Symptoms of the latter may include chills with or without fever, rash, leukopenia, purpura, arthralgia or arthritis, myalgia, generalized edema, malaise, mental changes, lymphadenopathy, splenomegaly, ECG changes indicative of myocarditis and albuminuria and hematuria. Interstitial nephritis has been reported. Other signs of hypersensitivity may include wheezing, flushing of the skin, pruritus, vasculitis of the skin or other organs, positive coomb's reactions, infrequently with hemolytic anemia, neutropenia, thrombocytopenia, eosinophilia, granulocytopenia and anemia. Infrequent effects may include jaundice, liver necrosis, central nervous system toxicity and neuropathy.

## 12. ECOLOGICAL INFORMATION

Not available

## 13. DISPOSAL CONSIDERATIONS

Dispose in accordance with all applicable regulations.

## 14. TRANSPORT INFORMATION

**U.S. DEPARTMENT OF TRANSPORTATION:** No classification assigned.

**CANADIAN TRANSPORTATION OF DANGEROUS GOODS:** No classification assigned.

**LAND TRANSPORT ADR:** No classification assigned.

**LAND TRANSPORT RID:** No classification assigned.

**AIR TRANSPORT IATA:** No classification assigned.

**AIR TRANSPORT ICAO:** No classification assigned.

**MARITIME TRANSPORT IMDG:** No classification assigned.

## 15. REGULATORY INFORMATION

**U.S. REGULATIONS:**
**CERCLA SECTIONS 102a/103 HAZARDOUS SUBSTANCES (40 CFR 302.4):** Not regulated.

**SARA TITLE III SECTION 302 EXTREMELY HAZARDOUS SUBSTANCES (40 CFR 355.30):** Not regulated.

**SARA TITLE III SECTION 304 EXTREMELY HAZARDOUS SUBSTANCES (40 CFR 355.40):** Not regulated.

**SARA TITLE III SARA SECTIONS 311/312 HAZARDOUS CATEGORIES (40 CFR 370.21):**
ACUTE: Yes
CHRONIC: Yes
FIRE: No
REACTIVE: No
SUDDEN RELEASE: No

**SARA TITLE III SECTION 313 (40 CFR 372.65):** Not regulated.

**OSHA PROCESS SAFETY (29CFR1910.119):** Not regulated.

**STATE REGULATIONS:**
**California Proposition 65:** Not regulated.

**CANADIAN REGULATIONS:**
**WHMIS CLASSIFICATION:** Not determined.

**EUROPEAN REGULATIONS:**
**EC CLASSIFICATION (CALCULATED):**

| | |
|---|---|
| Xn | Harmful |

**DANGER/HAZARD SYMBOL:**

Xn

**EC RISK AND SAFETY PHRASES:**

| | |
|---|---|
| R 42 | May cause sensitization by inhalation. |
| R 43 | May cause sensitization by skin contact. |

| | |
|---|---|
| R 64 | May cause harm to breastfed babies. |
| S 2 | Keep out of the reach of children. |
| S 24 | Avoid contact with skin. |
| S 46 | If swallowed, seek medical advice immediately and show this container or label. |

**NATIONAL INVENTORY STATUS:**
**U.S. INVENTORY (TSCA):** Not listed on inventory.

**TSCA 12(b) EXPORT NOTIFICATION:** Not listed.

## 16. OTHER INFORMATION

**MSDS SUMMARY OF CHANGES**
15. REGULATORY INFORMATION

ORIGINAL

# MATERIAL SAFETY DATA SHEET

## 1. CHEMICAL PRODUCT AND COMPANY IDENTIFICATION

**MDL INFORMATION SYSTEMS, INC.**
**1281 Murfreesboro Road, Suite 300**
**Nashville, TN 37217-2423**

**1-615-366-2000**

**EMERGENCY TELEPHONE NUMBER**
**1-800-424-9300 (NORTH AMERICA)**
**1-703-527-3887 (INTERNATIONAL)**

**SUBSTANCE: NAFCILLIN SODIUM**

**TRADE NAMES/SYNONYMS:**
4-THIA-1-AZABICYCLO(3.2.0)HEPTANE-2-CARBOXYLIC ACID, 6-(((2-ETHOXY-1-NAPHTHALENYL)CARBONYL)AMINO)-3,3-DIMETHYL-7-OXO-MONOSODIUM SALT, (2S-(2ALPHA,5ALPHA,6BETA))-; 4-THIA-1-AZABICYCLO(3.2.0)HEPTANE-2-CARBOXYLIC ACID, 6-(2-ETHOXY-1- NAPHTHAMIDO)-3,3-DIMETHYL-7-OXO-, MONOSODIUM SALT; (2S-(2ALPHA,5ALPHA,6BETA))-4-THIA-1-AZABICYCLO(3.2.0)HEPTANE-2- CARBOXYLIC ACID, 6-(((2-ETHOXY-1-NAPHTHALENYL)CARBONYL)AMINO)-3,3- DIMETHYL-7-OXO-MONOSODIUM SALT; 3,3-DIMETHYL-7-OXO-, 4-THIA-1-AZABICYCLO(3.2.0)HEPTANE-2-CARBOXYLIC ACID, 6-(2-ETHOXY-1-NAPHTHAMIDO) MONOSODIUM SALT; BRL1383; NAFCILLIN SODIUM SALT; NAFTOPEN; NAPHTHICILLIN; SODIUM NAFCILLIN; UNIPEN; WY 3277; 6-(2-ETHOXY-1-NAPHTHAMIDO)PENICILLIN SODIUM; SODIUM 6-(2-ETHOXY-1-NAPHTHAMIDO)PENICILLANATE; C21H21N2NAO5S; OHS16086; RTECS XI0175000

**CHEMICAL FAMILY:** antibiotic/antiseptic

**CREATION DATE:** Jul 13 1990
**REVISION DATE:** Jun 16 2005

## 2. COMPOSITION, INFORMATION ON INGREDIENTS

**COMPONENT:** NAFCILLIN SODIUM
**CAS NUMBER:** 985-16-0
**EC NUMBER (EINECS):** 213-574-4
**PERCENTAGE:** 100.0

## 3. HAZARDS IDENTIFICATION

**NFPA RATINGS (SCALE 0-4):** HEALTH=2 FIRE=1 REACTIVITY=0

**EMERGENCY OVERVIEW:**
**COLOR:** white
**PHYSICAL FORM:** powder
**ODOR:** faint odor
**MAJOR HEALTH HAZARDS:** allergic reactions
**PHYSICAL HAZARDS:** Dust/air mixtures may ignite or explode.

**POTENTIAL HEALTH EFFECTS:**
**INHALATION:**
**SHORT TERM EXPOSURE:** allergic reactions, asthma
**LONG TERM EXPOSURE:** same as effects reported in short term exposure
**SKIN CONTACT:**
**SHORT TERM EXPOSURE:** allergic reactions, asthma
**LONG TERM EXPOSURE:** same as effects reported in short term exposure
**EYE CONTACT:**
**SHORT TERM EXPOSURE:** allergic reactions
**LONG TERM EXPOSURE:** same as effects reported in short term exposure
**INGESTION:**
**SHORT TERM EXPOSURE:** same as effects reported in long term exposure, allergic reactions
**LONG TERM EXPOSURE:** rash, nausea, vomiting, diarrhea, stomach pain, chest pain, wheezing, asthma, dizziness, bluish skin color, lung congestion, blood disorders, convulsions

**CARCINOGEN STATUS:**
**OSHA:** No
**NTP:** No
**IARC:** No

## 4. FIRST AID MEASURES

**INHALATION:** If adverse effects occur, remove to uncontaminated area. Give artificial respiration if not breathing. Get immediate medical attention.

**SKIN CONTACT:** Wash skin with soap and water for at least 15 minutes while removing contaminated clothing and shoes. Get medical attention, if needed. Thoroughly clean and dry contaminated clothing and shoes before reuse.

**EYE CONTACT:** Flush eyes with plenty of water for at least 15 minutes. Then get immediate medical attention.

**INGESTION:** Contact local poison control center or physician immediately. Never make an unconscious person vomit or drink fluids. Give water, milk or activated charcoal slurry. Allow vomiting to occur. When vomiting occurs, keep head lower than hips to help prevent aspiration. If person is unconscious, turn head to side. Get medical attention immediately.

**ANTIDOTE:** penicillinase.

**NOTE TO PHYSICIAN:** For ingestion, consider gastric lavage.

## 5. FIRE FIGHTING MEASURES

**FIRE AND EXPLOSION HAZARDS:** Slight fire hazard. Dust/air mixtures may ignite or explode.

**EXTINGUISHING MEDIA:** regular dry chemical, carbon dioxide, water, regular foam

Large fires: Use regular foam or flood with fine water spray.

**FIRE FIGHTING:** Move container from fire area if it can be done without risk. Do not scatter spilled material with high-pressure water streams. Dike for later disposal. Use extinguishing agents appropriate for surrounding fire. Avoid inhalation of material or combustion by-products. Stay upwind and keep out of low areas.

## 6. ACCIDENTAL RELEASE MEASURES

**OCCUPATIONAL RELEASE:**
Collect spilled material in appropriate container for disposal. Keep out of water supplies and sewers. Keep unnecessary people away, isolate hazard area and deny entry.

## 7. HANDLING AND STORAGE

**STORAGE:** Store and handle in accordance with all current regulations and standards. Keep separated from incompatible substances.

## 8. EXPOSURE CONTROLS, PERSONAL PROTECTION

**EXPOSURE LIMITS:**
**NAFCILLIN SODIUM:**
No occupational exposure limits established.

**VENTILATION:** Provide local exhaust ventilation system. Ensure compliance with applicable exposure limits.

**EYE PROTECTION:** Wear splash resistant safety goggles. Provide an emergency eye wash fountain and quick drench shower in the immediate work area.

**CLOTHING:** Wear appropriate chemical resistant clothing.

**GLOVES:** Wear appropriate chemical resistant gloves.

**RESPIRATOR:** Under conditions of frequent use or heavy exposure, respiratory protection may be needed. Respiratory protection is ranked in order from minimum to maximum. Consider warning properties before use.
Any supplied-air respirator with a full facepiece that is operated in a pressure-demand or other positive-pressure mode.
Any self-contained breathing apparatus that has a full facepiece and is operated in a pressure-demand or other positive-pressure mode.
**For Unknown Concentrations or Immediately Dangerous to Life or Health -**
Any supplied-air respirator with full facepiece and operated in a pressure-demand or other positive-

pressure mode in combination with a separate escape supply.
Any self-contained breathing apparatus with a full facepiece.

## 9. PHYSICAL AND CHEMICAL PROPERTIES

**PHYSICAL STATE:** solid
**COLOR:** white
**PHYSICAL FORM:** powder
**ODOR:** faint odor
**MOLECULAR WEIGHT:** 436.46
**MOLECULAR FORMULA:** C21-H21-N2-O5-S.NA
**BOILING POINT:** Not applicable
**MELTING POINT:** Not available
**VAPOR PRESSURE:** Not applicable
**VAPOR DENSITY:** Not applicable
**SPECIFIC GRAVITY:** Not available
**WATER SOLUBILITY:** soluble
**PH:** 5.0-7.0 (3% solution)
**VOLATILITY:** Not applicable
**ODOR THRESHOLD:** Not available
**EVAPORATION RATE:** Not applicable
**COEFFICIENT OF WATER/OIL DISTRIBUTION:** Not available
**SOLVENT SOLUBILITY:**
**Soluble:** chloroform, alcohol

## 10. STABILITY AND REACTIVITY

**REACTIVITY:** Stable at normal temperatures and pressure.

**CONDITIONS TO AVOID:** Avoid heat, flames, sparks and other sources of ignition. Avoid contact with incompatible materials.

**INCOMPATIBILITIES:** oxidizing materials

NAFCILLIN SODIUM:
OXIDIZERS (STRONG): Fire and explosion hazard.

**HAZARDOUS DECOMPOSITION:**
Thermal decomposition products: oxides of carbon, nitrogen, sulfur, sodium

**POLYMERIZATION:** Will not polymerize.

## 11. TOXICOLOGICAL INFORMATION

**NAFCILLIN SODIUM:**
**TOXICITY DATA:**
>5 gm/kg oral-rat LD50; >5 gm/kg oral-mouse LD50; 1140 mg/kg intravenous-mouse LD50; 1240 mg/kg intraperitoneal-rat LD50; 600 mg/kg intraperitoneal-dog LD50; 2800 mg/kg intramuscular-rat

LD50; 3200 mg/kg/20 day(s) intermittent intravenous-woman TDLo; 4560 mg/kg/19 day(s) intermittent intravenous-woman TDLo; 450 mg/kg/3 day(s) intravenous-child TDLo; 3100 mg/kg/18 day(s) intermittent intravenous-man TDLo; 429 mg/kg/23 day(s) intermittent intravenous-man TDLo; 1 gm/kg intravenous-mouse LD50; 633 mg/kg intravenous-dog LD50; 1266 mg/kg intraperitoneal-mammal LD50; 2955 mg/kg intramuscular-mammal LD50
**ACUTE TOXICITY LEVEL:** Insufficient Data.
**TARGET ORGANS:** immune system (sensitizer)
**MEDICAL CONDITIONS AGGRAVATED BY EXPOSURE:** immune system disorders or allergies, respiratory disorders
**ADDITIONAL DATA:** May cross the placenta. May be excreted in breast milk. Interactions with drugs may occur. May cross react with similar compounds.

**HEALTH EFFECTS:**
**INHALATION:**
NAFCILLIN SODIUM: See information on penicillins.

**ACUTE EXPOSURE:**
PENICILLINS: On rare occasions, anaphylactic shock, as detailed in ingestion, has resulted from the inhalation of penicillins in sensitive individuals. Bronchoconstriction and asthma may occur.

**CHRONIC EXPOSURE:**
PENICILLINS: Repeated exposure may result in sensitization.

**SKIN CONTACT:**
NAFCILLIN SODIUM: See information on penicillins.

**ACUTE EXPOSURE:**
PENICILLINS: Topical administration of penicillins has produced serious hypersensitivity reactions such as angioedema with marked swelling of the lips, tongue, face and periorbital tissues, asthmatic breathing and giant hives. Intradermal instillation of very small quantities in skin testing has resulted in anaphylaxis and death in sensitized individuals.

**CHRONIC EXPOSURE:**
PENICILLINS: Repeated contact may result in sensitization. Allergic contact dermatitis has been reported from handling penicillins or the repeated topical application of penicillin ointments.

**EYE CONTACT:**
NAFCILLIN SODIUM: See information on penicillins.

**ACUTE EXPOSURE:**
PENICILLINS: The penicillins have had a high incidence of contact allergic reactions when applied topically.

**CHRONIC EXPOSURE:**
PENICILLINS: Repeated contact may result in sensitization and polyarthralgia ecchymosis.

**INGESTION:**
NAFCILLIN SODIUM: See information on penicillins.

**ACUTE EXPOSURE:**
PENICILLINS: In non-allergic persons, even large doses are generally non-toxic. Hypersensitivity

reactions, immediate and/or delayed, may occur in individuals without known prior exposure and may be due to unrecognized exposure to penicillin in the environment. These reactions may include anaphylaxis, angioedema and serum sickness type reactions; symptoms are described in chronic exposure.

**CHRONIC EXPOSURE:**
PENICILLINS: Repeated ingestion of penicillins may cause nausea with or without vomiting, epigastric distress, mild to severe diarrhea, sore or dry mouth, sore or black hairy tongue. Pseudomembranous colitis has been reported rarely. The most severe immediate hypersensitivity reaction is anaphylactic shock, which although usually associated with parenteral administration, has occurred with ingestion. Symptoms, which can occur within minutes, may include urticaria, purpuric skin lesions, localized edema, extreme weakness, dizziness, nausea, vomiting, diarrhea, abdominal pain and cramps, bronchoconstriction with severe asthma, chest pain, severe hypotension, cyanosis, circulatory collapse, pulmonary edema, convulsions and death in respiratory failure. Some individuals may have angioedema with marked swelling of the lips, tongue, face and periorbital tissues, asthmatic breathing and giant hives. Other immediate reactions may include laryngeal edema, laryngospasm and bronchospasm. Delayed reactions may include various skin rashes, ranging from maculopapular to exfoliative dermatitis, and serum sickness type reactions. Symptoms of the latter may include chills with or without fever, rash, leukopenia, purpura, arthralgia or arthritis, myalgia, generalized edema, malaise, mental changes, lymphadenopathy, splenomegaly, ECG changes indicative of myocarditis and albuminuria and hematuria. Interstitial nephritis has been reported. Other signs of hypersensitivity may include wheezing, flushing of the skin, pruritus, vasculitis of the skin or other organs, positive coomb's reactions, infrequently with hemolytic anemia, neutropenia, thrombocytopenia, eosinophilia, granulocytopenia and anemia. Infrequent effects may include jaundice, liver necrosis, central nervous system toxicity and neuropathy.

## 12. ECOLOGICAL INFORMATION

Not available

## 13. DISPOSAL CONSIDERATIONS

Dispose in accordance with all applicable regulations.

## 14. TRANSPORT INFORMATION

**U.S. DEPARTMENT OF TRANSPORTATION:** No classification assigned.

**CANADIAN TRANSPORTATION OF DANGEROUS GOODS:** No classification assigned.

**LAND TRANSPORT ADR:** No classification assigned.

**LAND TRANSPORT RID:** No classification assigned.

**AIR TRANSPORT IATA:** No classification assigned.

**AIR TRANSPORT ICAO:** No classification assigned.

ORIGINAL

**MARITIME TRANSPORT IMDG:** No classification assigned.

## 15. REGULATORY INFORMATION

**U.S. REGULATIONS:**
**CERCLA SECTIONS 102a/103 HAZARDOUS SUBSTANCES (40 CFR 302.4):** Not regulated.

**SARA TITLE III SECTION 302 EXTREMELY HAZARDOUS SUBSTANCES (40 CFR 355.30):** Not regulated.

**SARA TITLE III SECTION 304 EXTREMELY HAZARDOUS SUBSTANCES (40 CFR 355.40):** Not regulated.

**SARA TITLE III SARA SECTIONS 311/312 HAZARDOUS CATEGORIES (40 CFR 370.21):**
ACUTE: Yes
CHRONIC: Yes
FIRE: No
REACTIVE: No
SUDDEN RELEASE: No

**SARA TITLE III SECTION 313 (40 CFR 372.65):** Not regulated.

**OSHA PROCESS SAFETY (29CFR1910.119):** Not regulated.

**STATE REGULATIONS:**
**California Proposition 65:** Not regulated.

**CANADIAN REGULATIONS:**
**WHMIS CLASSIFICATION:** Not determined.

**EUROPEAN REGULATIONS:**
**EC CLASSIFICATION (CALCULATED):**

| | |
|---|---|
| Xn | Harmful |

**DANGER/HAZARD SYMBOL:**

**Xn**

**EC RISK AND SAFETY PHRASES:**

| | |
|---|---|
| R 42 | May cause sensitization by inhalation. |
| R 43 | May cause sensitization by skin contact. |
| R 64 | May cause harm to breastfed babies. |
| S 2 | Keep out of the reach of children. |
| S 24 | Avoid contact with skin. |
| S 46 | If swallowed, seek medical advice immediately and show this container or label. |

ORIGINAL

**NATIONAL INVENTORY STATUS:**
**U.S. INVENTORY (TSCA):** Not listed on inventory.

**TSCA 12(b) EXPORT NOTIFICATION:** Not listed.

## 16. OTHER INFORMATION

**MSDS SUMMARY OF CHANGES**
15. REGULATORY INFORMATION

ORIGINAL

# MATERIAL SAFETY DATA SHEET

## 1. CHEMICAL PRODUCT AND COMPANY IDENTIFICATION

**MDL INFORMATION SYSTEMS, INC.**
**1281 Murfreesboro Road, Suite 300**
**Nashville, TN 37217-2423**

**1-615-366-2000**

**EMERGENCY TELEPHONE NUMBER**
**1-800-424-9300 (NORTH AMERICA)**
**1-703-527-3887 (INTERNATIONAL)**

**SUBSTANCE: PENICILLIN G PROCAINE MONOHYDRATE**

**TRADE NAMES/SYNONYMS:**
4-THIA-1-AZABICYCLO(3.2.0)HEPTANE-2-CARBOXYLIC ACID, 3,3-DIMETHYL-7- OXO-6-((PHENYLACETYL)AMINO)-(2S-(2ALPHA,5ALPHA,6BETA))-, COMPD. WITH 2-(DIETHYLAMINO)ETHYL 4-AMINOBENZOATE (1:1), MONOHYDRATE; 4-THIA-1-AZABICYCLO(3.2.0)HEPTANE-2-CARBOXYLIC ACID, 3,3-DIMETHYL-7- OXO-6-(2-PHENYLACETAMIDO)-, COMPD. WITH 2-(DIETHYLAMINO)ETHYL P-AMINO BENZOATE (1:1), MONOHYDRATE; (2S-(2ALPHA,5ALPHA,6BETA))-4-THIA-1-AZABICYCLO(3.2.0) HEPTANE-2-CAR- OXYLIC ACID, 3,3-DIMETHYL-7-OXO-6-((PHENYLACETYL)AMINO)-, COMPD. WITH 2-(DIETHYLAMINO)ETHYL 4-AMINOBENZOATE (1:1), MONOHYDRATE; 3,3-DIMETHYL-7-OXO-6-(2-PHENYLACETAMIDO)-4-THIA-1-AZABICYCLO(3.2.0) HEPTANE-2-CARBOXYLIC ACID, COMPD. WITH 2-(DIETHYLAMINO)ETHYL P-AMINO- BENZOATE (1:1), MONOHYDRATE; ABBOCILLIN-DC; AFSILLIN; AMPIN-PENCILLIN; CILICAINE; PROCAINE PENICILLIN G MONOHYDRATE; PRO-PEN; WYCILLIN; C29H40N4O7S; OHS84260; RTECS XH9450000

**CHEMICAL FAMILY:** antibiotic/antiseptic

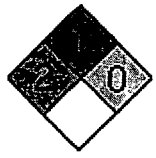
**CREATION DATE:** Jul 13 1990
**REVISION DATE:** Jun 16 2005

## 2. COMPOSITION, INFORMATION ON INGREDIENTS

**COMPONENT:** PENICILLIN G PROCAINE MONOHYDRATE
**CAS NUMBER:** 6130-64-9
**EC NUMBER:** Not assigned.
**PERCENTAGE:** 100.0

## 3. HAZARDS IDENTIFICATION

**NFPA RATINGS (SCALE 0-4):** HEALTH=2 FIRE=1 REACTIVITY=0




**EMERGENCY OVERVIEW:**
**COLOR:** white
**PHYSICAL FORM:** crystalline powder, crystals
**ODOR:** odorless
**MAJOR HEALTH HAZARDS:** allergic reactions
**PHYSICAL HAZARDS:** Dust/air mixtures may ignite or explode.

**POTENTIAL HEALTH EFFECTS:**
**INHALATION:**
**SHORT TERM EXPOSURE:** allergic reactions, asthma
**LONG TERM EXPOSURE:** same as effects reported in short term exposure
**SKIN CONTACT:**
**SHORT TERM EXPOSURE:** irritation, allergic reactions
**LONG TERM EXPOSURE:** same as effects reported in short term exposure
**EYE CONTACT:**
**SHORT TERM EXPOSURE:** irritation, allergic reactions
**LONG TERM EXPOSURE:** same as effects reported in short term exposure
**INGESTION:**
**SHORT TERM EXPOSURE:** allergic reactions
**LONG TERM EXPOSURE:** rash, nausea, vomiting, diarrhea, stomach pain, chest pain, wheezing, asthma, dizziness, bluish skin color, lung congestion, blood disorders, convulsions

**CARCINOGEN STATUS:**
**OSHA:** No
**NTP:** No
**IARC:** No

## 4. FIRST AID MEASURES

**INHALATION:** If adverse effects occur, remove to uncontaminated area. Give artificial respiration if not breathing. Get immediate medical attention.

**SKIN CONTACT:** Wash skin with soap and water for at least 15 minutes while removing contaminated clothing and shoes. Get medical attention, if needed. Thoroughly clean and dry contaminated clothing and shoes before reuse.

**EYE CONTACT:** Flush eyes with plenty of water for at least 15 minutes. Then get immediate medical attention.

**INGESTION:** If swallowed, drink plenty of water, do NOT induce vomiting. Get immediate medical attention. Induce vomiting only at the instructions of a physician. Do not give anything by mouth to unconscious or convulsive person.

**ANTIDOTE:** penicillinase. For anaphylactic reactions, epinephrine; steroids, intravenous.

**NOTE TO PHYSICIAN:** For ingestion, consider gastric lavage, activated charcoal slurry and catharsis.

## 5. FIRE FIGHTING MEASURES

**FIRE AND EXPLOSION HAZARDS:** Slight fire hazard. Dust/air mixtures may ignite or explode.

**EXTINGUISHING MEDIA:** regular dry chemical, carbon dioxide, water, regular foam

Large fires: Use regular foam or flood with fine water spray.

**FIRE FIGHTING:** Move container from fire area if it can be done without risk. Do not scatter spilled material with high-pressure water streams. Dike for later disposal. Use extinguishing agents appropriate for surrounding fire. Avoid inhalation of material or combustion by-products. Stay upwind and keep out of low areas.

## 6. ACCIDENTAL RELEASE MEASURES

**OCCUPATIONAL RELEASE:**
Collect spilled material in appropriate container for disposal. Keep out of water supplies and sewers. Keep unnecessary people away, isolate hazard area and deny entry.

## 7. HANDLING AND STORAGE

**STORAGE:** Store and handle in accordance with all current regulations and standards. Keep separated from incompatible substances.

## 8. EXPOSURE CONTROLS, PERSONAL PROTECTION

**EXPOSURE LIMITS:**
**PENICILLIN G PROCAINE MONOHYDRATE:**
No occupational exposure limits established.

**VENTILATION:** Provide local exhaust ventilation system. Ventilation equipment should be explosion-resistant if explosive concentrations of material are present. Ensure compliance with applicable exposure limits.

**EYE PROTECTION:** Wear splash resistant safety goggles with a faceshield. Provide an emergency eye wash fountain and quick drench shower in the immediate work area.

**CLOTHING:** Wear appropriate chemical resistant clothing.

**GLOVES:** Wear appropriate chemical resistant gloves.

**RESPIRATOR:** Under conditions of frequent use or heavy exposure, respiratory protection may be needed. Respiratory protection is ranked in order from minimum to maximum. Consider warning properties before use.
Any supplied-air respirator with a full facepiece that is operated in a pressure-demand or other positive-pressure mode.
Any self-contained breathing apparatus that has a full facepiece and is operated in a pressure-demand or other positive-pressure mode.

**For Unknown Concentrations or Immediately Dangerous to Life or Health -**
Any supplied-air respirator with full facepiece and operated in a pressure-demand or other positive-pressure mode in combination with a separate escape supply.
Any self-contained breathing apparatus with a full facepiece.

## 9. PHYSICAL AND CHEMICAL PROPERTIES

**PHYSICAL STATE:** solid
**COLOR:** white
**PHYSICAL FORM:** crystalline powder, crystals
**ODOR:** odorless
**MOLECULAR WEIGHT:** 588.72
**MOLECULAR FORMULA:** C16-H18-N2-O4-S.C13-H20-N2-O2.H-O-H
**BOILING POINT:** Not applicable
**MELTING POINT:** Not available
**DECOMPOSITION POINT:** 223-230 F (106-110 C)
**VAPOR PRESSURE:** Not applicable
**VAPOR DENSITY:** Not applicable
**SPECIFIC GRAVITY:** Not available
**WATER SOLUBILITY:** very slightly soluble
**PH:** 5.0-7.5
**VOLATILITY:** Not applicable
**ODOR THRESHOLD:** Not available
**EVAPORATION RATE:** Not applicable
**COEFFICIENT OF WATER/OIL DISTRIBUTION:** Not available
**SOLVENT SOLUBILITY:**
**Moderately Soluble:** chloroform, methanol
**Slightly Soluble:** isopropanol, toluene, ethyl acetate
**Very Slightly Soluble:** benzene, petroleum ether, carbon tetrachloride

## 10. STABILITY AND REACTIVITY

**REACTIVITY:** Stable at normal temperatures and pressure.

**CONDITIONS TO AVOID:** Avoid heat, flames, sparks and other sources of ignition. Avoid contact with incompatible materials.

**INCOMPATIBILITIES:** oxidizing materials

PENICILLIN G PROCAINE MONOHYDRATE:
OXIDIZERS (STRONG): Fire and explosion hazard.

**HAZARDOUS DECOMPOSITION:**
Thermal decomposition products: oxides of carbon, nitrogen, sulfur

**POLYMERIZATION:** Will not polymerize.

## 11. TOXICOLOGICAL INFORMATION

**PENICILLIN G PROCAINE MONOHYDRATE:**
**TOXICITY DATA:**
4 mg/kg intramuscular-man TDLo; >6 gm/kg subcutaneous-rat LD50; 97 mg/kg intravenous-rat LD50; >2 gm/kg oral-mouse LD50; 146 mg/kg intraperitoneal-mouse LD50; 2300 mg/kg subcutaneous-mouse LD50; 119 mg/kg intravenous-mouse LD50; >1 gm/kg intramuscular-mouse LD50; >545 mg/kg subcutaneous-dog LDLo; 70 mg/kg intravenous-rabbit LD50
**ACUTE TOXICITY LEVEL:** Insufficient Data.
**TARGET ORGANS:** immune system (sensitizer)
**MEDICAL CONDITIONS AGGRAVATED BY EXPOSURE:** immune system disorders or allergies, kidney disorders
**ADDITIONAL DATA:** May cross the placenta. May be excreted in breast milk. Interactions with drugs may occur. May cross react with similar compounds.

**HEALTH EFFECTS:**
**INHALATION:**
PENICILLIN G PROCAINE: See information on penicillins.

**ACUTE EXPOSURE:**
PENICILLINS: On rare occasions, anaphylactic shock, as detailed in ingestion, has resulted from the inhalation of penicillins in sensitive individuals. Bronchoconstriction and asthma may occur.

**CHRONIC EXPOSURE:**
PENICILLINS: Repeated exposure may result in sensitization.

**SKIN CONTACT:**
PENICILLIN G PROCAINE: See information on penicillins. In addition, irritation and numbness have been reported.

**ACUTE EXPOSURE:**
PENICILLINS: Topical administration of penicillins has produced serious hypersensitivity reactions such as angioedema with marked swelling of the lips, tongue, face and periorbital tissues, asthmatic breathing and giant hives. Intradermal instillation of very small quantities in skin testing has resulted in anaphylaxis and death in sensitized individuals.

**CHRONIC EXPOSURE:**
PENICILLINS: Repeated contact may result in sensitization. Allergic contact dermatitis has been reported from handling penicillins or the repeated topical application of penicillin ointments.

**EYE CONTACT:**
PENICILLIN G PROCAINE: See information on penicillins. In addition, irritation has been reported.

**ACUTE EXPOSURE:**
PENICILLINS: The penicillins have had a high incidence of contact allergic reactions when applied topically.

**CHRONIC EXPOSURE:**
PENICILLINS: Repeated contact may result in sensitization and polyarthralgia ecchymosis.

**INGESTION:**
PENICILLIN G PROCAINE: See information on penicillins.

**ACUTE EXPOSURE:**
PENICILLINS: In non-allergic persons, even large doses are generally non-toxic. Hypersensitivity reactions, immediate and/or delayed, may occur in individuals without known prior exposure and may be due to unrecognized exposure to penicillin in the environment. These reactions may include anaphylaxis, angioedema and serum sickness type reactions; symptoms are described in chronic exposure.

**CHRONIC EXPOSURE:**
PENICILLINS: Repeated ingestion of penicillins may cause nausea with or without vomiting, epigastric distress, mild to severe diarrhea, sore or dry mouth, sore or black hairy tongue. Pseudomembranous colitis has been reported rarely. The most severe immediate hypersensitivity reaction is anaphylactic shock, which although usually associated with parenteral administration, has occurred with ingestion. Symptoms, which can occur within minutes, may include urticaria, purpuric skin lesions, localized edema, extreme weakness, dizziness, nausea, vomiting, diarrhea, abdominal pain and cramps, bronchoconstriction with severe asthma, chest pain, severe hypotension, cyanosis, circulatory collapse, pulmonary edema, convulsions and death in respiratory failure. Some individuals may have angioedema with marked swelling of the lips, tongue, face and periorbital tissues, asthmatic breathing and giant hives. Other immediate reactions may include laryngeal edema, laryngospasm and bronchospasm. Delayed reactions may include various skin rashes, ranging from maculopapular to exfoliative dermatitis, and serum sickness type reactions. Symptoms of the latter may include chills with or without fever, rash, leukopenia, purpura, arthralgia or arthritis, myalgia, generalized edema, malaise, mental changes, lymphadenopathy, splenomegaly, ECG changes indicative of myocarditis and albuminuria and hematuria. Interstitial nephritis has been reported. Other signs of hypersensitivity may include wheezing, flushing of the skin, pruritus, vasculitis of the skin or other organs, positive coomb's reactions, infrequently with hemolytic anemia, neutropenia, thrombocytopenia, eosinophilia, granulocytopenia and anemia. Infrequent effects may include jaundice, liver necrosis, central nervous system toxicity and neuropathy.

## 12. ECOLOGICAL INFORMATION

Not available

## 13. DISPOSAL CONSIDERATIONS

Dispose in accordance with all applicable regulations.

## 14. TRANSPORT INFORMATION

**U.S. DEPARTMENT OF TRANSPORTATION:** No classification assigned.

**CANADIAN TRANSPORTATION OF DANGEROUS GOODS:** No classification assigned.

**LAND TRANSPORT ADR:** No classification assigned.

**LAND TRANSPORT RID:** No classification assigned.

**AIR TRANSPORT IATA:** No classification assigned.

**AIR TRANSPORT ICAO:** No classification assigned.

**MARITIME TRANSPORT IMDG:** No classification assigned.

## 15. REGULATORY INFORMATION

**U.S. REGULATIONS:**
**CERCLA SECTIONS 102a/103 HAZARDOUS SUBSTANCES (40 CFR 302.4):** Not regulated.

**SARA TITLE III SECTION 302 EXTREMELY HAZARDOUS SUBSTANCES (40 CFR 355.30):** Not regulated.

**SARA TITLE III SECTION 304 EXTREMELY HAZARDOUS SUBSTANCES (40 CFR 355.40):** Not regulated.

**SARA TITLE III SARA SECTIONS 311/312 HAZARDOUS CATEGORIES (40 CFR 370.21):**
ACUTE: Yes
CHRONIC: Yes
FIRE: No
REACTIVE: No
SUDDEN RELEASE: No

**SARA TITLE III SECTION 313 (40 CFR 372.65):** Not regulated.

**OSHA PROCESS SAFETY (29CFR1910.119):** Not regulated.

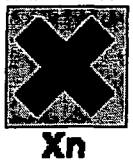
**STATE REGULATIONS:**
**California Proposition 65:** Not regulated.

**CANADIAN REGULATIONS:**
**WHMIS CLASSIFICATION:** Not determined.

**EUROPEAN REGULATIONS:**
**EC CLASSIFICATION (CALCULATED):**

| | |
|---|---|
| Xn | Harmful |

**DANGER/HAZARD SYMBOL:**



**Xn**

**EC RISK AND SAFETY PHRASES:**

| | |
|---|---|
| R 42 | May cause sensitization by inhalation. |
| R 43 | May cause sensitization by skin contact. |
| R 64 | May cause harm to breastfed babies. |
| S 2 | Keep out of the reach of children. |